ENGINEERING

- Display of Biologics
- Engineering Antibodies
- Machine Learning - Part 2

TARGETS

- Antibody-Based Therapies
- Emerging Targets & Approaches
- Membrane Protein Targets

BISPECIFICS

- Safety and Efficacy of Bispecifics
- Advancing Bispecifics
- Engineering Bispecifics

IMMUNOTHERAPY

- Tumour Microenvironment
- Innovations in CAR Therapy
- Next-Gen Immunotherapies

ANALYTICAL

- Optimisation & Developability
- Analytical Characterisation
- Protein Stability & Formulation

EXPRESSION

- Cell Line Engineering
- Expression Platforms
- Process Development

MACHINE LEARNING

- Intro to Machine Learning
- Machine Learning - Part 2
- Machine Learning - Part 1

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PLENARY KEYNOTE

Benchmarking the Impact of AI Biologics Discovery and Optimisation for Pharma

Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

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CONFERENCE AT-A-GLANCE

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TARGETS		Antibody-Based Therapies	Emerging Targets & Approaches	Membrane Protein Targets
BISPECIFICS		Safety and Efficacy of Bispecifics	Advancing Bispecifics	Engineering Bispecifics
IMMUNOTHERAPY		Tumour Microenvironment	Innovations in CAR Therapy	Next-Gen Immunotherapies
ANALYTICAL		Optimisation & Developability	Analytical Characterisation	Protein Stability & Formulation
EXPRESSION		Cell Line Engineering	Expression Platforms	Protein Process Development
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Training SEMINARS By Cambridge Healthtech Institute		TS7A: Introduction to Machine Learning for Biologics Design TS8A: Introduction to Bispecific Antibodies: History, Engineering, and Application TS9A: Introduction to Protein Engineering		

*Separate registration required for short courses.

The best biologics technology meeting in Europe. A must-attend conference for novel biologics.

Rakesh D., PhD
President & CEO, Bionavigen

PLENARY KEYNOTE SESSION

15 NOVEMBER 2023 | 10:10-11:00

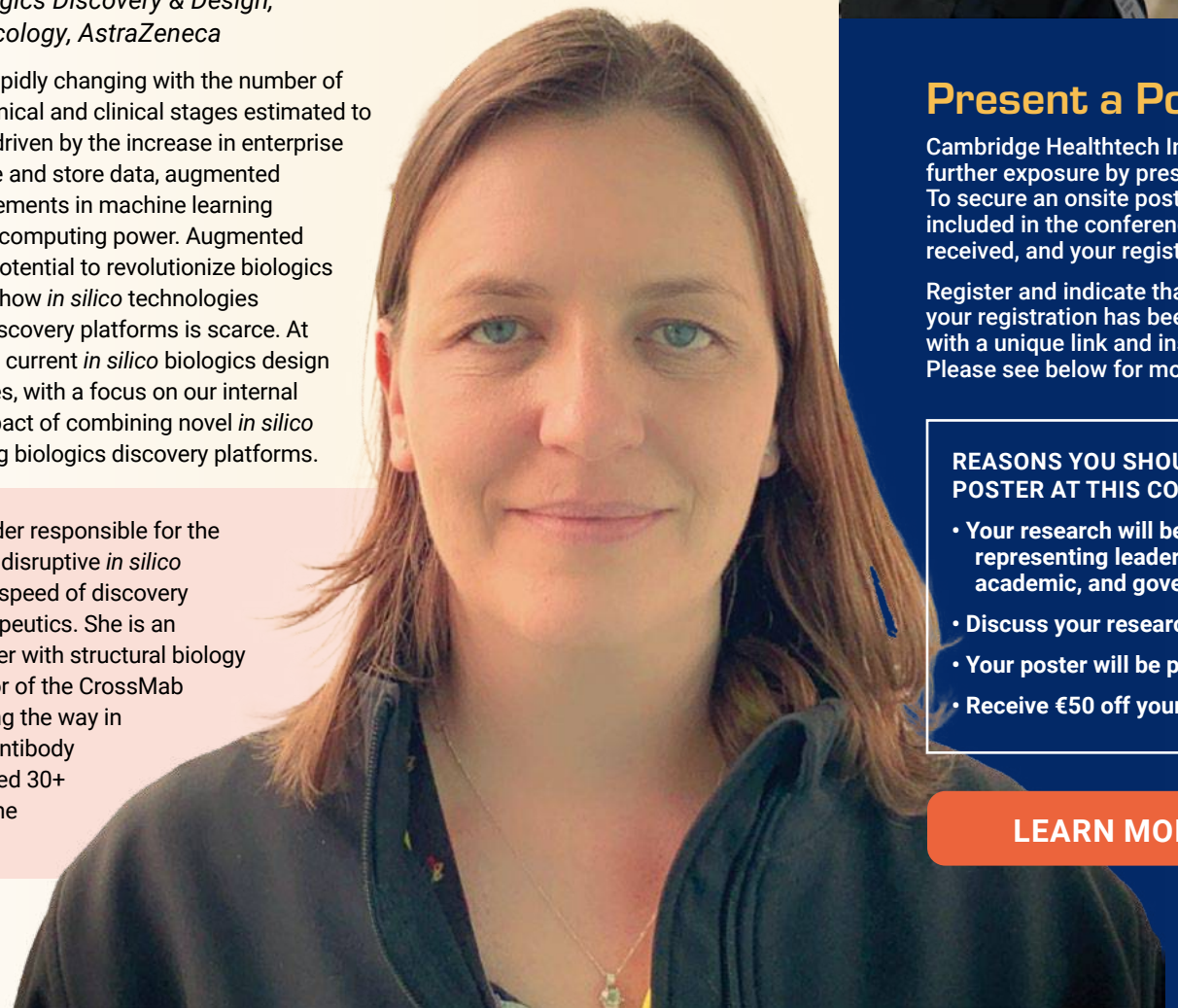
Benchmarking the Impact of AI Biologics Discovery & Optimisation for Pharma

Rebecca Croasdale-Wood, PhD

Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

The biologics landscape is rapidly changing with the number of AI-enabled biologics in preclinical and clinical stages estimated to be 50-60 (1). This change is driven by the increase in enterprise software solutions to capture and store data, augmented discovery workflows, improvements in machine learning technology, and advances in computing power. Augmented biologics discovery has the potential to revolutionize biologics discovery, yet information of how *in silico* technologies perform, versus traditional discovery platforms is scarce. At PEGS Europe, we will present current *in silico* biologics design and optimisation technologies, with a focus on our internal efforts to benchmark the impact of combining novel *in silico* technologies with our existing biologics discovery platforms.

Rebecca is an innovative leader responsible for the implementation of novel and disruptive *in silico* technologies to increase the speed of discovery and quality of biologics therapeutics. She is an experienced antibody engineer with structural biology expertise and was co-inventor of the CrossMab technology that is now leading the way in approvals for multi-specific antibody therapeutics. She has authored 30+ patents and publications in the field of antibody engineering.



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SHORT COURSES * | MONDAY, 13 NOVEMBER

All short courses will take place in-person only

SC1: Machine Learning Tools for Protein Engineering

Instructor:
Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo

In silico prediction, engineering, and design are changing how large-molecule drugs (proteins) will be discovered, designed, and optimized. However, these tools are still in early development, and much needs to be learned on how to adapt them for use in antibody and vaccine discovery, training, prediction, developability, simulation, and optimization. This short course highlights the rapid growth and availability of machine learning techniques and tools for protein engineering.

SC2: Developability of Bispecific Antibodies: Formats and Applications

Instructor:
Nimish Gera, PhD, Vice President, Biologics, Mythic Therapeutics

Bispecific antibodies are a rapidly growing and clinically validated class of antibodies with marketed drugs and multiple candidates in clinical trials. Targeting multiple antigens in a synergistic manner can confer enhanced therapeutic benefit and potentially uncover novel biological mechanisms. However, multiple formats and a tedious candidate selection process to select functional and developable bispecific antibodies makes such programs cumbersome. This short course highlights the rapid growth in the field, therapeutic applications, and focuses on challenges with discovery and development of bispecific antibodies. We will use an approved bispecific antibody as a case study to understand the varied aspects of discovery and development of bispecific antibody programs.

SC4: The Use and Optimization of Eukaryotic Expression Systems to Support Therapeutic Generation and Structural Biology

Instructors:
Richard Altman, MS, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific
Henry C. Chiou, PhD, Senior Director General Manager, Biosciences, Thermo Fisher Scientific
Barbara Fernandes, Scientist, TCA, iBET Instituto de Biologia Experimental Tecnologica

Eukaryotic expression systems are extensively used for the generation of recombinant proteins thereby becoming an essential protein engineering tool. The choice of a suitable eukaryotic expression system depends mainly on the biological and biochemical properties of an individual protein. The course will focus on both the insect and mammalian expression systems, which have demonstrated the ability to express complex proteins for a wide variety of applications. We will discuss the concepts, uses, and optimization of these systems along with sharing experimental troubleshooting lessons learned. The course combines instruction and case studies in an interactive environment.

SC5: Best Practices for Targeting GPCRs, Ion Channels, and Transporters with Monoclonal Antibodies

Instructor:
Joseph Rucker, PhD, Vice President, Research and Development, Integral Molecular, Inc.

Complex membrane proteins are important therapeutic targets and together represent the majority of protein classes addressed by therapeutic drugs. Significant opportunities exist for targeting complex membrane proteins with antibodies, but it has been challenging to discover therapeutic antibodies against them. This course will examine emerging technologies and strategies for enabling the isolation of specific and functional antibodies against GPCRs, ion channels, and transporters, and highlight progress via case studies.

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All training seminars will take place in-person only

TS7A: Introduction to Machine Learning for Biologics Design

Instructor:
Christopher R. Corbeil, PhD, Research Officer, Human Health Therapeutics, National Research Council Canada

This course offers an introduction to concepts, strategies, and machine learning methods used for biologics design. It includes presentations and demonstrations of the methods used in the field, covering techniques such as triaging sequences, modulating affinity, and designing antibody libraries, along with increasing manufacturability. The course is directed at scientists new to the field and protein engineers wanting an introduction to how machine learning can aid in guiding biologics design.

TOPICS TO BE COVERED:

- Basics of machine learning and where it fits into drug discovery
- Machine learning: a historical view of its application in the field of drug discovery
- How machine learning revolutionized homology modeling
- Applying machine learning to structure-based biologics design
- Guiding the design of display libraries using machine learning

TS8A: Introduction to Bispecific Antibodies: History, Engineering, and Application

Instructor:
G. Jonah Rainey, PhD, Senior Director, Protein Engineering, Eli Lilly and Company

Introduction to Bispecific Antibodies will be organized as an informative and practical guide to getting up to speed on critical aspects of bispecific antibody therapeutics. Topics will include historical successes, failures, and lessons learned. Specific practical instruction will span mechanisms of action, engineering, developability, regulatory considerations, and translational guidelines. Perspectives on ideal implementation of bispecifics as targeted and immunomodulatory approaches will be discussed.

TOPICS TO BE COVERED:

- A brief history of bispecific antibodies: 60 years of progress with critical advances and key pioneers
- Bispecific applications and powerful mechanisms of action Engineering bispecific antibodies:100 formats and counting
- Bispecific-specific considerations in preclinical development and regulatory landscape
- Developability, manufacturing, and analytical considerations Clinical experience, translation, and regulatory approval
- Current trends and future opportunities in regulating immune checkpoints, cell-based therapies, and personalized approaches

TS9A: Introduction to Protein Engineering

Instructor:
David Bramhill, PhD, Founder, Bramhill Biological Consulting LLC

The seminar presents a comprehensive tutorial in the concepts, strategies, and latest tools of protein engineering applied to biotherapeutic research and development, particularly antibody-related products. The class is for scientists new to industry or working in support roles, academics, and protein scientists wanting a detailed update on the current state of the field.

TOPICS TO BE COVERED:

What Is Protein Engineering?

- Functions amenable to engineering: affinity, specificity, catalysis, stability, solubility, immunogenicity, serum half-life
- The Future of Protein Engineering

Tools and Techniques

- The measure of success: functional assays
- Engineering by design
- Engineering by random mutation
- Designed libraries display technologies
- Deep sequencing applications in analyzing libraries and repertoires

Production and Manufacturing

- Evaluating biotherapeutic developability
- Improving manufacturing by protein engineering methods
- Glycosylation engineering — function and homogeneity
- Other protein modifications
- Immunogenicity engineering and humanization
- Expression of antibodies and fragments for discovery and testing
- Manufacturing platforms for antibodies and fragments

Emerging Molecule and Product Formats

- Bispecific antibodies/binders
- Antibody-drug conjugates (ADCs)
- CAR T strategies
- Other emerging constructs

10TH ANNUAL | LISBON, PORTUGAL

DISPLAY OF BIOLOGICS

Leading the Way for New Classes of Therapy

TUESDAY 14 NOVEMBER

7:30 Registration Open and Morning Coffee

ADDRESSING DIFFICULT TARGETS WITH DISPLAY TECHNOLOGIES

8:25 Chairperson's Remarks
Ahuva Nissim, PhD, Professor, Antibody and Therapeutic Engineering, William Harvey Research Institute, Queen Mary University of London

8:30 KnotBodies: Creating Ion Channel Modulating Antibodies by Fusing Knottins into Antibody Loops
John D. McCafferty, PhD, Scientific Advisor, IONTAS; CEO and Founder, Maxion Therapeutics

Venom derived cysteine-rich miniproteins (knottins) have potential as therapeutic agents to block ion channels but suffer from manufacturing difficulties, short half-lives and a lack of specificity. Maxion have developed a novel molecular format wherein the knottin replaces a peripheral CDR loop of an antibody. This format (termed KnotBody™), combines the best features of both molecular classes. The presentation illustrates the generation of KnotBody inhibitors of multiple ion channels.

9:00 KEYNOTE PRESENTATION: Antibodies Binding to GPCRs in Different Conformations
Andreas G. Plueckthun, PhD, Professor & Head, Biochemistry, University of Zurich

G protein-coupled receptors are important drug targets for agonists and antagonists, depending on the application. We have carried out a massive selection of antibody Fab fragments against one GPCR using different strategies, and we have now been able to determine the structure of many different GPCR-Fab complexes at high resolution with cryo-EM. This wide range of different complexes allows unprecedented insight into receptor conformations and how to stabilize them.

9:30 A Library Approach for the *de novo* High-Throughput Isolation of Humanized VHH Domains with Favorable Developability Properties Following Camelid Immunization
Andreas Evers, PhD, Principal Scientist, Computational Chemistry & Biology, Global Research & Development Discovery Technology, Merck Healthcare KGaA

We have generated a novel library approach for high-throughput *de novo* identification of humanized single-domain antibodies following camelid immunization. We demonstrate that by exploiting this approach, humanized high-affinity sdAbs with an optimized *in silico* developability profile can be generated that display favorable biophysical, biochemical, and functional attributes and do not require any further sequence optimization.

10:00 Talk Title to be Announced
Mart Ustav Jr, PhD, CSO, Icosagen

10:30 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

CONDITIONALLY ACTIVATED BIOLOGICS

11:14 Chairperson's Remarks
E. Sally Ward, PhD, Director, Translational Immunology; Professor, Molecular Immunology, Centre for Cancer Immunology, University of Southampton

11:15 From Clustering Activated Agonists to SWITCH-DARPins
Daniel Steiner, PhD, Vice President, Lead Generation, Molecular Partners AG

Immune cell-engaging drugs show great patient value, and have pathed the way for next-generation molecules optimized for depth and duration of response. For the most potent of these molecules, disease-restricted activation will be key. We will present an update on our DARPin-based tumor-activated FAPxCD40 program and introduce a novel SWITCH-DARPin approach, allowing disease-restricted activation based exclusively on the binding of tumor targets.

11:45 ALG.APV-527: Design of a Bispecific Tumor Antigen-Conditional 4-1BB x 5T4 Agonist that Mediates Strong T Cell Activation and Potent Anti-Tumor Activity
Peter Ellmark, PhD, CSO, Alligator Bioscience AB

ALG.APV-527 was generated by incorporating binders obtained from the Alligator GOLD library into Aptevos ADAPTIR format, and was designed for 5T4-conditional 4-1BB-mediated anti-tumor activity. Preclinical *in vitro* and *in vivo* models demonstrate potential to minimize systemic immune activation and hepatotoxicity, while providing efficacious tumor-specific responses. ALG.APV-527 has potential as a promising anti-cancer therapeutic for the treatment of 5T4-expressing tumors, and is currently evaluated in a Phase 1 study.

12:15 Pioneer and Spylock: The Fastest Route to Mono- and Bi-Specific Therapeutic Antibodies
Francisco Ylera, R&D Team Lead, Bio-Rad

Bio-Rad's Pioneer Antibody Discovery Platform includes one of the largest Fab libraries ever made. The library contains over 2 x 10^11 unique human antibody sequences and has been extensively optimized for Fab selection and for IgG developability. In combination with the proprietary SpyDisplay selection technology and with the TrailBlazer modular antibody platform, Pioneer enables rapid identification and characterization of a diverse set of lead candidates. We will also introduce SpyLock, a novel approach for generation and early screening of bispecific antibodies with unprecedented speed and throughput.

12:45 Session Break

12:55 LUNCHEON PRESENTATION: Writing the Future of Biologics with an Integrated Offering of Immunization, Libraries, and Machine Learning
Aaron K. Sato, PhD, CSO, Twist Bioscience

Twist Biopharma Solutions, a division of Twist Bioscience, combines HT DNA synthesis technology with expertise in antibody engineering to provide end-to-end antibody discovery solutions — from gene synthesis to antibody optimization. The result is a make-test cycle that yields better antibodies against challenging targets from immunization, libraries, and machine learning.

10TH ANNUAL | LISBON, PORTUGAL

DISPLAY OF BIOLOGICS

Leading the Way for New Classes of Therapy

13:25 LUNCHEON PRESENTATION: Data-Driven Discovery Made Easy, Scalable, and Ready for the ML Era

Piotr van Rijssel, Application Scientist, ENPICOM

NGS and high-throughput screening tools are now mainstream in antibody discovery, generating valuable data that many research teams struggle to fully leverage. Join us to discuss the essential elements of modern data-driven discovery and how we incorporate them in the IGX Platform for identifying promising antibody leads. Additionally, we will explore strategies to make ML-aided discovery accessible through ENPICOM's expertise or your in-house ML capabilities.

13:55 Session Break

SELECTING DISPLAY TECHNOLOGY FOR DEVELOPABILITY

14:05 Chairperson's Remarks

René M.A. Hoet, PhD, Chief Innovation Officer, FairJourney Biologics

14:10 When Evolutionary Distance Matters: Generation of Mono- and Multi-Specific Humanized Antibodies by Chicken Immunization and Yeast Display Screening

Harald Kolmar, PhD, Professor and Head, Institute for Organic Chemistry and Biochemistry, Technische Universität Darmstadt

We generated a platform for the discovery of antibodies by chicken immunization, followed by transfer of antibody diversity, to yeast for surface display screening (YSD). Antibodies with broad epitope coverage are obtained. Common light chain antibodies can be isolated for modular assembly of multi-specifics. CDR transplantation to a human framework with partial randomization of signature residues, followed by YSD screening of high-affinity variants, allows for straightforward humanization.

14:40 Mammalian Antibody Display: Microfluidic Hit Discovery and Their Fruitful Combination

Achim Doerner, PhD, Principal Scientist, Protein Engineering & Antibody Technologies, Merck Healthcare KGaA

Mammalian display libraries can be interrogated consecutively for manufacturability and specificity. Pre-enriched libraries secreting antibodies are a perfect match for microfluidics-assisted high-throughput screening. Options for (and recent advances in) combining these emerging technologies will be discussed.

15:10 New Technology Developments for Future (Multi-Specific) Antibody Discovery and Optimization

René Hoet, PhD, Professor, Chief Innovation Officer, FairJourney Biologics

New Large Explorer Modular semi-synthetic Phage Library with potential antibody diversity of 1.10E+27. Propriety Mammalian Display Technology to optimize antibodies and multi-specifics for optimized developability, Easy Transfer from Explorer to Mammalian Display & Expression to Optimize Ab Repertoires in Final Ab Format and deliver therapeutic lead candidates.

15:40 A Humanized Chicken Antibody Platform that Delivers Diverse and Developable Therapeutic Candidates

Joseph Rucker, PhD, Vice President, Research & Development, Integral Molecular

Highly conserved proteins frequently represent valuable, yet elusive, targets for antibody discovery due to immune tolerance across mammalian hosts. We discuss how chicken immunizations solve this problem and deliver antibodies with broad epitope coverage and long HCDR3 regions able to access functional pockets. Our chicken-based discovery platform includes technology for simultaneous humanization and affinity maturation and has produced high-affinity, highly developable antibodies against conserved targets including claudin 6, CCR8 and GLUT4.

16:10 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Selecting Novel Antibody Leads against SLC Transporters Using the Linkster Discovery Platform

Iwan Zimmermann, PhD, CSO, Linkster Therapeutics AG

Antibody discovery against ion channels, GPCRs, and SLC transporters is very challenging. Failing drug campaigns, leading to non-developable antibodies, are often associated with display technology unfit for low target stability, and uncontrolled conditions. Here, case studies using the Linkster discovery platform demonstrate that developable and highly stable, conformation-specific antibody starting points can be reliably generated within 3 weeks, through smart library design and novel selection and screening technology.

NOVEL SELECTION STRATEGIES OF ANTIBODIES

17:29 Chairperson's Opening Remarks

Joao Goncalves, PhD, Full Professor, Microbiology & Immunology, University of Lisbon

17:30 Discovering Functional Modulators of the Ion Channel Kv1.3 from Engineered Peptide and Antibody Libraries

Bill D. Harriman, PhD, Senior Vice President, Antibody Discovery, OmniAb, Inc.

Synthetic antibody libraries were designed featuring ShK, a natural peptide that is a potent modulator of the ion channel Kv1.3, as the CDRH3 region of a cow VH domain. ShK sequence variants were engineered to enhance specificity for Kv1.3 over Kv1.1. Library hits were evaluated for activity and specificity in high-throughput e-phys studies, and compared to mAbs from cow antibody libraries, and from engineered chickens producing human sequence antibodies.

18:00 Selection and Validation of TCR-Like Antibodies and TCRs for Adoptive Therapy

Reno Debets, PhD, Professor, Chair, Tumor Immunology Lab, Medical Oncology, Erasmus MC Cancer Center

CAR T cell products have entered mainstream therapy of leukemias. To build on these real-world successes, and expand adoptive therapy to solid tumors, there is need for tumor-selective targets, as well as strategies to create or retrieve receptors that recognize such targets. In this presentation, the selection and validation of targets, and more specifically, corresponding receptors is highlighted-including TCR-like antibodies, as well as TCRs directed against cancer-selective peptide: MHCs.

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Display of Biologics Conference

8TH ANNUAL | LISBON, PORTUGAL

ENGINEERING ANTIBODIES

Designing the Next Best-in-Class Biologics

WEDNESDAY 15 NOVEMBER

7:30 Registration Open and Morning Coffee

NOVEL PLATFORMS

8:25 Chairperson's Opening Remarks
Lars Linden, PhD, Vice President, Head, Biologics Research, Bayer HealthCare AG

8:30 KEYNOTE PRESENTATION: Discovery of Antibody-Based Therapeutics to Challenging Targets: Platform Considerations
Agnieszka Kielczewska, PhD, Director, Research, Antibody Discovery and Screening, Biologics Discovery, Amgen, Canada

Discovery of large molecule-based therapeutics to complex targets requires diverse approaches. Previously, we applied an internally developed enhanced hybridoma platform, which enabled deep interrogation of *in vivo* derived immune repertoires. Today, we transitioned to B cell discovery, accessing differential compartments in the immunized animal, and supplementing with mammalian display to solve immunologically intractable targets. High-precision B cell technologies coupled with display and NGS sequencing form the foundation of our discovery engine.

9:00 Biology-Based Engineering of Versatile Antibody and Albumin Technologies
Jan Terje Andersen, PhD, Professor, Department of Pharmacology, University of Oslo; Research Group Leader, Department of Immunology, Oslo University Hospital

The long plasma half-life of IgG and albumin is regulated by a broadly expressed receptor, FcRn. As such, insights into how FcRn is transporting its ligands within and across cellular layers have implications for design of modalities that directly or indirectly engage the receptor. I will discuss how this complex biology can be explored in engineering of albumin and antibody formats that enhance or restrict transport across cellular barriers.

9:30 Solve Bispecific Heavy-Light Chain Mispairing with bYlok Technology Lonza
Peter O'Callaghan, PhD, Head of Expression System Sciences, Biologics and Licensing, Lonza

Lonza's bYlok® technology is an innovative solution that drives correct heavy-light chain pairing rates in IgG-like bispecifics to 95%. This improves yields of the correct species and streamlines downstream processing, without affecting key performance attributes of the molecule. In this talk, we present new case studies of bYlok engineered bispecifics and explore how bYlok stacks up against other established pairing solutions. We'll also show how elements of the GS toolbox can be used to increase yields of such engineered molecules.

10:00 Session Break to Transition into Plenary Keynote

PLENARY KEYNOTE SESSION

10:10 Plenary Keynote Introduction
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

10:15 Benchmarking the Impact of AI Biologics Discovery and Optimisation for Pharma
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

At PEGS Europe, we will present current *in silico* biologics design and optimisation technologies, with a focus on our internal efforts to benchmark the impact of combining novel *in silico* technologies with our existing biologics discovery platforms.

10:45 Keynote Chat
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

10:45 Plenary Fireside Chat
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

11:00 Coffee Break in the Exhibit Hall with Poster Viewing

BISPECIFIC AND MULTI-SPECIFIC ANTIBODIES

11:45 UniStac: Enzyme-Mediated Conjugation Technology for Accelerated Development of Tetraspecific NASH Drug
Sungjin Park, PhD, CEO, Onegene Biotechnology

UniStac, a novel enzyme-mediated protein-protein conjugation technology, streamlines multi-target drug development by conjugating two proteins into single Y-shaped, antibody-like molecules, bypassing Fc heteromerization optimization. The successful large-scale production of OGB21502, a leading tetraspecific NASH drug, achieved at a 1000 L, underscores its industrial feasibility. UniStac's rapid development enables the efficient exploration of tri- and tetraspecific combinations with any modality choices, in a true plug-and-play mode.

12:15 Programmable DNA-Origami-Based T Cell Engagers: PTE
Klaus Wagenbauer, PhD, Founder & CEO, Plectonic

Modular and programmable assemblies of various antibody formats on DNA-origami nanocarriers yield stable multi-specific antibody-DNA hybrids. Quadruplet T cell engagers efficiently activate T cells *in vitro* and target and lyse tumor cells *in vivo* in a xenograft mouse tumor model. This approach enables rapid generation, screening, and testing of multi-specific programmable next-generation immune cell engagers for preclinical pharmaceutical development.

12:45 Anti-GARP/TGFb1 Antibodies in a New Twist – Multifunctional Shapers of Anti-Tumor Immunity evitria
Damian Trojanowski, Dr, R&D Specialist, Antibody Discovery Group, Pure Biologics

High GARP/TGFβ-1 surface expression on both Tregs and cancer cells results in LTGFβ-1 activation and TGFβ-1-induced immunosuppression in the tumor microenvironment. This correlates with poor prognosis and treatment failures in several human cancers. Pure Biologics developed fully human anti-GARP/TGFβ-1 IgGs and bispecifics with enhanced ADCC properties. These molecules demonstrate a multi-modal tumour killing by overcoming TGFβ-1-induced immunosuppression. This talk explores the discovery and development work performed with support from evitria AG.

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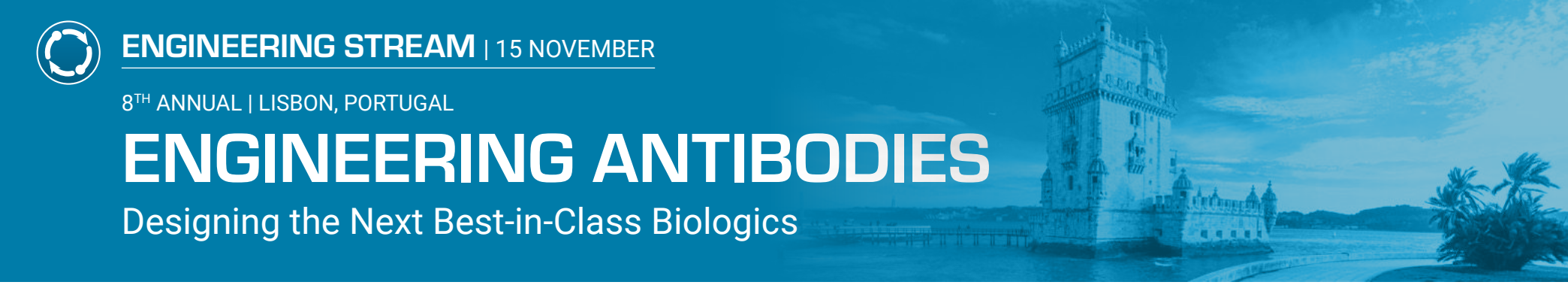
ENGINEERING ANTIBODIES

Designing the Next Best-in-Class Biologics



13:15 Session Break

13:20 LUNCHEON PRESENTATION: The Antibody Discovery Journey: from Next-Generation Libraries to Efficacy and Safety

charles river

Maurice Brozzo, Global Antibody Specialist, Charles River

The therapeutic antibody discovery journey is a complex process with numerous potential stumbling blocks. Starting with next-generation fully human antibody libraries consisting of therapeutic ready molecules dramatically increases the chances of success. Using a bioinformatics approach the Charles River libraries have been carefully designed and contain selected frameworks for increased developability and highly diverse CDRs for optimal binding properties. The selection of the final therapeutic antibody is supported by sophisticated characterization methods which assess efficacy and safety to determine the best therapeutic candidate.

13:50 LUNCHEON PRESENTATION II: Leveraging Integrated & Advanced Technologies for Successful Cell Line Development

SARTORIUS

Gail Calvert, Field Application Scientist, Sartorius UK Ltd.

This presentation focuses on early-stage CLD with instrumentation for high-throughput screening and enabling identification of clones. Integrated technologies like the CellCelector, iQue and Octet platforms are perfectly designed to work together to streamline the CLD workflow, enabling data-driven decisions and reducing risk during later stages of biologics development.The talk highlights the instruments strengths, capabilities and where they fit into the CLD workflow.

14:20 Session Break

ENGINEERING FOR HIGHER AVIDITY AND MULTI-VALENCY

14:30 Chairperson's Remarks

Bruce Keyt, PhD, CSO, R&D, IGM Biosciences, Inc.

14:35 IgM Antibodies as Receptor Cross-Linking Agents for DR-5 and Other TNF Targets

Bruce Keyt, PhD, CSO, R&D, IGM Biosciences, Inc.

Engineered IgMs have high affinity, strong avidity, and robust receptor cross-linking capability. Agonist IgMs can trimerize TNF-type receptors, exhibiting more than 1000x increased apoptotic activity, compared to corresponding IgGs. IgMs are highly structured, and with appropriate epitope selection, antibodies can be developed with best-in-class safety, with wide therapeutic index. We will provide updates on research and clinical status of IGM-8444 (anti-DR5 IgM) for treatment of colorectal carcinoma.

15:05 Avidity Engineering: A Next Frontier in the Development of Differentiating Antibody Therapeutics

Simone Oostindie, PhD, Director, Research and Discovery, Gyes B.V.

This presentation explores the concept of antibody avidity engineering, which involves optimizing multivalent interactions of antibodies with their targets to unlock novel functionalities and mechanisms-of-action, offering new opportunities for developing differentiated antibody therapeutics with enhanced selectivity and potency.

15:35 Accelerating Functional TCR Discovery by Phenotyping Thousands of Live, Single T Cells in Two Days

BRUKER

Troy Lionberger, PhD, Senior Vice President, Business Development, Bruker

This presentation will introduce a high-throughput screening technology platform capable of observing single T cells in co-culture with antigen-presenting cells (APCs). During the time-course observation, >1,000 single T cells are monitored for their ability to kill APCs in co-culture, surface marker expression, and cytokine secretion. Recovering functional T cells from patient samples using this two-day workflow can accelerate therapeutic TCR discovery, T cell vaccine development, and patient immune monitoring.

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

ENGINEERING FOR PRECISION TARGETING, AFFINITY, AND DEVELOPABILITY

17:00 Molecule Formats for Tumour Targeting of Radiotherapies

Lars Linden, PhD, Vice President, Head, Biologics Research, Bayer HealthCare AG

Successful tumor treatment with Targeted Radio Therapies (TRTs) relies on the selection of the most appropriate combination of high-energy radio emitter, chelator, and linker, as well as tumor targeting moiety. Although TRTs share similarities with ADCs, their unique mode of action requires different strategies.

17:30 Engineering Hyperstable Synthetic Miniproteins as Developable Ligands

Benjamin J. Hackel, PhD, Professor, Chemical Engineering & Materials Science, University of Minnesota

Synthetic miniproteins are compelling scaffolds for binding ligands with advantageous modularity, physiological transport, and efficient synthesis. We have evaluated the developability and evolvability of >50 miniprotein libraries systematically varied across topology, framework, and paratope location. We evolved binders to eight targets and measured proxies of solubility, expression, and stability for millions of scaffold variants. The results elucidate biophysical factors that dictate miniprotein scaffold performance thereby empowering library and clone design.

18:00 Engineering Bicyclic Peptides for Precision Targeted Medicine

James Cooke, PhD, Associate Director, Bicycle Therapeutics

The Bicycle platform uses proprietary bicyclic peptide phage display technology to deliver a unique toolkit of building blocks to create novel medicines. Bicycles combine rapid extravasation and extensive tissue penetration with renal clearance and tuneable half-life. This talk describes how Bicycles targeted to tumour antigens are engineered, seeking to deliver cytotoxic or radionuclide payloads, or combined with immune agonist Bicycles to seek to deliver tumour killing as precision targeted medicines.

18:30 Learning Antibody Binding Affinity Using FACS and NGS

Iain H. Moal, PhD, Scientific Leader, Computational Antibody Engineering, GSK

An ML model was generated to accelerate the antibody selection from our yeast display platform by reducing the number of FACS/NGS rounds. The built model predicts the progression between rounds and therefore which mutations and combinations influence affinity.

19:00 Close of Engineering Antibodies Conference

2ND ANNUAL | LISBON, PORTUGAL

MACHINE LEARNING FOR PROTEIN ENGINEERING - PART 2

Demonstrating Value and Putting Theory into Practice

THURSDAY 16 NOVEMBER

7:30 Registration Open and Morning Coffee

PLM AND GENERATIVE MODELING FOR *DE NOVO* DESIGN

8:55 Chairperson's Remarks
Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo

9:00 Enhancing Antibody Discovery with Generative AI
Melody Shahsavarian, PhD, Digital Biologics Platform, Large Molecules Research, Sanofi
With a growing majority of its pipeline composed of biologics, there is an increasing need at Sanofi to bring more molecules to development at a faster pace. Generative AI and *in silico* screening methods provide opportunities to improve probability of success and decrease discovery-to-lead timelines. Combining deep repertoire mining technologies and generative ML modeling, we are building a *de novo* protein design platform and a more targeted drug discovery approach.

9:30 The Singular Immune Response to Dengue and Machine Learning Identification of Antibodies in High-Throughput Sequences
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET
Dengue virus is a threat to global health. However, no specific therapeutics are available so far. Broadly neutralizing antibodies recognizing the various serotypes could serve as potential treatment. High-throughput adaptive immune receptor repertoire high-throughput sequencing (AIRR-seq) and bioinformatic analyses enable in-depth understanding of the B cell immune response.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Protein Engineering with Large Language Models
Ali Madani, PhD, Founder and CEO, Profluent Bio
Generative models have shown promise in capturing the distribution of natural proteins. In this talk, we'll cover a research evolutionary trajectory of the application of large language models from natural language processing to functional protein design. We'll conclude with a look into future scaling and preliminary trends.

11:15 Computational Counterselection Identifies Nonspecific Therapeutic Biologic Candidates
Stefan Ewert, PhD, Associate Director, Biologics Center, Novartis Institutes for Biomedical Research
Biologics require high specificity for targets, but current affinity-selection-based discovery methods do not guarantee this property. We present a method, computational counterselection, that identifies nonspecific candidates using machine learning models of affinity trained on high-throughput data from single-target affinity selection experiments.

11:45 Applying Deep Learning Anomaly Detection to Antibody Structures
Hiroki Shirai, PhD, Coordinator, RIKEN Center for Computational Science
How to mitigate risks of antibody sequences especially generated with AI? Most of the methods for human-ness evaluation have a limitation due to the presence of V-D-J faults. We developed a method to evaluate human-ness from 2D pixel images of antibody structures using CNN-VAE, which is a technique used to detect outliers in factory-produced products. We also introduce a new method to improve conformational stability with a single mutation.

12:15 Computational Nanobody Binding Epitope prediction and Re-epitoping
Anne Goupil-Lamy, PhD, Science Council Fellow at BIOVIA, BIOVIA, Dassault Systèmes
Discover how molecular modeling and deep learning are transforming nanobody epitope mapping and re-epitoping, advancing precision antibody engineering for diverse applications in biotechnology and medicine.

12:45 Enjoy Lunch on Your Own

13:50 Dessert Break in the Exhibit Hall & Last Chance for Poster Viewing

14:45 Session Break

STRUCTURE, DOCKING, AND DYNAMICS FUNDAMENTALS

15:00 Chairperson's Remarks
Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo

15:05 Unconstrained Generation of Synthetic Antibody-Antigen Structures to Guide Machine Learning Methodology for Antibody Specificity Prediction
Rahmad Akbar, PhD, Researcher, Computational Systems Immunology, University of Oslo
Antibody structures inform and improve machine learning predictions. We devise a method for the parameter-based unconstrained generation of synthetic lattice-based three-dimensional antibody-antigen-binding structures. Our method provides ground-truth access to conformational paratope, epitope, and affinity. We showcase the utility of synthetic datasets to benchmark the real-world relevance of machine learning models for antibody binding prediction.

15:35 Third-Generation Approaches of Antibody Discovery and Optimisation
Pietro Sormanni, PhD, Group Leader, Royal Society University Research Fellow, Chemistry of Health, Yusuf Hamied Department of Chemistry, University of Cambridge
I will discuss emerging computational antibody design methods, which enable the targeted design of antibodies for predetermined epitopes and the prediction and modulation of their developability potential through the co-optimization of multiple biophysical properties. Overall, it is increasingly possible to complement well-established *in vivo* (first-generation) and *in vitro* (second-generation) methods of antibody discovery with *in silico* (third-generation) approaches, with time- and cost-saving benefits.

2ND ANNUAL | LISBON, PORTUGAL

MACHINE LEARNING FOR PROTEIN ENGINEERING - PART 2

Demonstrating Value and Putting Theory into Practice

NOVEL/ALTERNATIVE ML-ENABLED SCREENING TECHNOLOGIES FOR HIGHER POS

16:04 Chairperson's Remarks
M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, Inc.

16:05 scifAI: An Explainable Machine Learning Framework Applied to Functional Characterization of Therapeutic Antibodies
Fabian Schmich, PhD, Senior Data Scientist, pRED Informatics, Roche Diagnostics Deutschland GmbH
scifAI is a comprehensive, open-source explainable machine learning framework for the analysis of imaging flow cytometry data. In this presentation, I will focus on alterations to the immunological synapse, analyzing class frequency- and morphological changes of the cell, as well as showcasing the prediction of T cell cytokine production under stimulation with different antibodies, linking morphological features with function and thus demonstrating the potential to significantly impact antibody design.

16:35 Accelerating Antibody Development: Advancing Discovery through Integrated Bioinformatics and Machine Learning PipeBio
Jannick Bendtsen, CEO, PipeBio
Early-stage antibody discovery requires efficient and comprehensive approaches to identify promising candidates with optimal developability characteristics. This presentation explores how next-generation sequencing (NGS) analysis and machine learning can be applied to optimize antibody developability. We explore a practical implementation of analysis pipelines using PipeBio Bioinformatics Platform and illustrate the benefits of applying such analysis tools through case studies, showing their efficacy in expediting early-stage antibody discovery.

16:50 Low-Data Interpretable Deep Learning Prediction of Antibody Viscosity Using a Biophysically Meaningful Representation
Brajesh K. Rai, PhD, Senior Director, Machine Learning Computational Sciences, Pfizer Inc.
Deep learning has led to substantial advances across many disciplines. However, many scientific problems of practical interest lack sufficiently large datasets amenable to deep learning. Prediction of antibody viscosity is one such problem where these methods have not yet been explored due to the relative scarcity of relevant training data. We will describe how we have overcome this limitation using a biophysically meaningful representation to develop generalizable deep learning models.

17:20 Integrating Single-Cell Immune Repertoire Sequencing, Machine Learning, and Biophysical Properties of Antibodies
Alexander Yermanos, PhD, Lecturer, Systems & Synthetic Immunology, ETH Zurich
Immune repertoires represent a diverse collection of B and T cell receptors which interact with a seemingly infinite number of molecular structures. Recent advancements in deep sequencing and microfluidics allow high-throughput recovery of paired heavy- and light-chain sequences, thereby linking computational features of immune repertoires to biophysical properties of antibodies at an unprecedented resolution. I will explore the intersection of repertoires, ML, and biophysical features like antigen-specificity, affinity, and epitope.

17:50 PANEL DISCUSSION: Current State of AI in Antibody Therapeutics: The Promise, the Reality and the Hype
Co-Moderators:
M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, Inc.
Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo
Panelists:
Andrew R.M. Bradbury, PhD, CSO, Specifica, Inc.
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca
René M.A. Hoet, PhD, Chief Innovation Officer, FairJourney Biologics
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

18:30 Close of PEGS Europe Summit

INAUGURAL | LISBON, PORTUGAL

ANTIBODY-BASED CANCER THERAPIES

Recent Advances and Future Directions

TUESDAY 14 NOVEMBER

7:30 Registration Open and Morning Coffee

KEYNOTE PRESENTATION

8:25 Chairperson's Remarks
Gregory P. Adams, PhD, CSO, Elucida Oncology, Inc.

8:30 KEYNOTE PRESENTATION: Antibody Chain-Exchange-Based Approaches to Generate and Optimize Bispecific Antibodies, Prodrugs, and ADCs
Ulrich Brinkmann, PhD, Expert Scientist, Pharma Research & Early Development, Roche Innovation Center, Munich
Antibody chain exchange approaches base on separate entities with partially repulsive domain interfaces that recombine to products with optimal interfaces. This technology was initially developed to provide large binder-format matrices of bispecific antibodies and identify combinations with optimal functionalities. The presentation will show that the principles of such technologies can also be applied to generate antibody-payload matrices and antibody-prodrugs.

ANTIBODY-DRUG CONJUGATES

9:00 Inducing Significant and Efficient Tumour Growth Inhibition vs. Trastuzumab Deruxtecan Using Two Different Topo1 Inhibitors (DAR4) and Peptide Linkers for Payload Conjugation to Trastuzumab
Philipp Spycher, PhD, CEO, Araris Biotech AG
A novel peptide linker technology will be introduced that enables site-specific linker-payload conjugation to native antibodies in one step. The resulting ADCs show remarkable *in vivo* stability and antibody-like PK exposure. ADCs carrying topoisomerase-1 inhibitors were generated at various drug-load ratios including an ADC with two different Topo-1 payloads that showed superior efficacy vs trastuzumab deruxtecan in a challenging, moderate HER2-expressing animal model.

9:30 Evaluation of Fcab-Drug Conjugates as a Novel Antibody-based Format for Targeted Drug Delivery
Sebastian Jaeger, PhD, Senior Scientist, ADCs & Targeted NBE Therapeutics, Merck Healthcare KGaA
Fcab-Drug Conjugates are a novel ADC format carrying an Fc antigen binding fragment (Fcab) as targeting scaffold instead of an IgG antibody. The combination of Fcabs' small size, antigen binding capabilities, and relatively long half-life makes them a promising scaffold for the generation of drug conjugates with improved tissue penetration capabilities compared to classical IgG-based ADCs. This talk covers the concept and format exploration data.

10:00 A New Era of Single-cell Functional Profiling for Drug Discovery. lightcast
Kathrin Herbst, PhD, Director of Science & Business Development, Lightcast
At Lightcast we are developing a novel, programmable microfluidic platform that allows precise and highly flexible control of individual microdroplets using software-generated light patterns. Within drug development, this can accelerate functional characterisation and shorten optimisation time in Antibody Discovery and T-Cell workflows. Furthermore, as droplets remain individually addressable throughout, live cells of interest can be rapidly dispensed for downstream assays.

10:30 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:15 First-in-Human Study of ELU001, a Targeted C'Dot Drug Conjugate, in Subjects with Folate Receptor α (FRα) Overexpressing Solid Tumors
Gregory P. Adams, PhD, CSO, Elucida Oncology, Inc.
ELU001 is a C'Dot Drug Conjugate (CDC), a targeted ultra-small (~6nm diameter) nanoparticle composed of a silica core, a layer of short PEG chains conjugated to ~21 exatecan payload and ~13 folic acid targeting moieties. The safety and efficacy results of Elucida's first in human study with ELU001 will be presented.

11:45 Preclinical Profile of BYON3521 Predicts an Effective and Safe MET ADC
Patrick G Groothuis, PhD, Principal Scientist, Byondis B V
This presentation will discuss the nonclinical pharmacology of the MET-targeting ADC BYON3521.

12:15 POSTER HIGHLIGHT: Development of a Novel Trispecific Antibody for the Anticancer Immune Targeting of Non-Hodgkin Lymphoma
Margarida Ferreira-Silva, PhD, Junior Researcher, Faculty of Veterinary Medicine, University of Lisbon
Advances in T-cell-based immunotherapies resulted in unprecedented clinical responses. Nevertheless, most patients remain unresponsive to immunotherapy. Bispecific antibodies that bind to tumor targets and cytotoxic T-cells are promising immunotherapies. However, providing co-stimulatory signals may improve T-cell responses. Herein, we develop a trispecific antibody targeting canine CD20, CD3 and CD28 for improved activation and sustained T-cell response against canine non-Hodgkin lymphoma.

12:30 POSTER HIGHLIGHT: ROR1 Targeted 4-1BB Conditional Bispecific Antibody, ABL102, Exhibits Potent *in vitro* and *in vivo* Antitumor Activity and Superior Safety Profile
Yangsoon Lee, PhD, Sr Dir, R&D, ABL Bio Inc
ABL102, a novel bispecific antibody targeting ROR1 and 4-1BB, activates 4-1BB in tumor microenvironment. ABL102 exhibited potent anti-tumor activity across several tumor types and induced protective memory. ABL102 induced immune cell infiltration and Treg depletion in tumors without triggering systemic immune response. ABL102 was well tolerated and safe in the NHP toxicity study. These results strongly suggest that ABL102 is a promising therapeutic for ROR1-positive cancer patients.

12:45 Session Break

12:55 LUNCHEON PRESENTATION: Evolutionary Intelligence in Antibody Library Design and Discovery Q² Solutions
Andrew Bradbury, MB BS, PhD, Chief Scientific Officer, Specifica, Inc.
Evolutionary Intelligence uses the "intelligence" encoded within antibody CDR sequences to design libraries and improve pre-existing antibodies. As only well-folded antibodies form part of B cell receptors, CDRs from such antibodies can fold correctly within germline compatible antibody frameworks. This is the rationale for our antibody library and improvement platform, which uses germline matched CDRs, purged of sequence liabilities, as diversity sources for different naïve library formats.

INAUGURAL | LISBON, PORTUGAL

ANTIBODY-BASED CANCER THERAPIES

Recent Advances and Future Directions

13:25 LUNCHEON PRESENTATION II: Use Multi-Parameter Characterization to Profile Developability Characteristics Unique to ADC's

Stefanie Kall, Ph.D., Sr. Marketing Product Manager, Product, NanoTemper Technologies

There are unique concerns about the developability properties of antibody-drug conjugates (ADCs) due to the conjugation process. With multi-parameter assessment of CQAs, it is possible to examine multiple aspects of ADC stability in parallel, to ensure the final product has the greatest chance at clinical success, while saving time and sample early in development. The case study presented here will deep dive into the practical considerations of ADC development and characterization.

13:55 Session Break

INTRACELLULAR, BISPECIFIC, AND LOGIC-GATED ANTIBODIES

14:05 Chairperson's Remarks

Rob N. de Jong, PhD, Senior Director and Head, Antibody Format Development, Genmab BV

14:10 Intracellular Antibodies for Drug Discovery against Hard-to-Drug Targets

Terence Rabbitts, FRS, FMedSci, Professor, Molecular Immunology, Center for Cancer Drug Discovery, Institute of Cancer Research

Intracellular antibodies are a starting point as inhibitors via design to block protein-protein interactions or to carry effector functions. Expressing fusions of intracellular antibodies with E3 ligase creates biodegraders to eliminate target proteins, or with procaspases to cause antigen-dependent cell death. The targeting LMO2 and mutant RAS is POC for intracellular antibodies as drugs per se.

14:40 Glycan and Novel Targets for Bispecific Cancer Therapy

Mireille Vankemmelbeke, PhD, Principal Scientist, Biodiscovery, Scancell, Ltd.

Antibody therapy based on glycan targets remains attractive. We will present preclinical results from reformatting these antibodies to T cell redirecting bispecifics, ADC, as well as their potential for CAR therapy; showcasing their versatility. Combination therapy may be warranted for optimising their efficacy towards solid tumours.

15:10 HexElect: Logic-Gated Antibody Pairs That Selectively Act on Cells Co-Expressing Two Antigens

Rob N. de Jong, PhD, Senior Director and Head, Antibody Format Development, Genmab BV

Genmab's HexElect technology is based on Fc-domain engineered IgG antibody pairs that act as Bio-Logic, and gates selectively activated after hetero-oligomerization. Functional activation of complement or signaling by HexElect antibody pairs was stringently dependent on the presence of two targets co-expressed at the same cell surface. HexElect technology may enable access to an untapped, combinatorial target space for the generation of antibody therapeutics that exhibit both selectivity and potency.

15:40 Evotec's integrated Biologics continuum to strengthen immunotherapy discovery programs

Thierry Wurch, PhD, SVP Integrated Biologics Discovery and Development, Head, Antibody discovery, Evotec (France) SAS

16:10 Refreshment Break in the Exhibit Hall with Poster Viewing

CONDITIONALLY ACTIVE BIOLOGICS

17:00 Conditionally Active Antibodies in Immuno-Oncology: Selectively Targeting VISTA in the Tumor Microenvironment

Edward van der Horst, PhD, CSO, Sensei Bio

SNS-101 is a conditionally active anti-VISTA antibody designed to relieve T cell suppression driven by the VISTA-PSGL-1 immune checkpoint within the acidic tumor-microenvironment, currently in a Phase I study. SNS-101 displayed strong anti-tumor activity in syngeneic tumor models as both monotherapy and in combination with PD-1 blockade. pH-selective target engagement resulted in a significantly improved safety and pharmacokinetic profile in non-human primates, suggesting SNS-101 may overcome prior hurdles of anti-VISTA biologics.

17:30 A Novel Tumor-Selective Anti-CD137 Agonist Antibody Activated by Elevated Extracellular ATP in Tumor Microenvironment

Ryo Uchikawa, Pharmacologist, Chugai Pharmaceutical Co., Ltd.

STA551 is a clinically investigated anti-CD137 agonist antibody that activates immune cells only in the presence of extracellular ATP. Previous study showed a synergistic efficacy of combining STA551 with anti-PD-L1 antibody. Using scRNA-seq, I tried to elucidate the mechanism and found this effect was due to an increase in activated T cells and a decrease in exhausted T cells. I would like to discuss the detail mechanism of action of STA551.

18:00 POSTER HIGHLIGHT: Impact of Antibody Architecture and Paratope Valency on Effector Functions of Bispecific NKp30 x EGFR NK Cell Engagers

Ammelie Svea Boje, Graduate Student, Antibody Based Immunotherapy, Universitaetsklinikum Schleswig Holstein

Novel NK cell engagers (NKCE) based on NKp30-targeting single domain antibodies (sdAb) that redirect the cytotoxic potential of NK cells towards EGFR-expressing tumor cells were generated. The impact of crucial parameters such as sdAb location, binding valencies, the targeted epitope on NKp30 as well as the overall antibody architecture on the redirection capacity were investigated. Our findings reveal novel insights for the engineering of potent NKCE triggering the NKp30 axis.

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Antibody-Based Cancer Therapies Conference

7TH ANNUAL | LISBON, PORTUGAL

EMERGING TARGETS AND THERAPEUTIC APPROACHES

Exploring Unconventional Approaches for Clinical Success in Oncology and Beyond

WEDNESDAY 15 NOVEMBER

7:30 Registration Open and Morning Coffee

INNOVATIVE APPROACHES TO THE CHALLENGES OF SOLID TUMOURS

8:25 Chairperson's Opening Remarks
Kerry Chester, PhD, Professor, Molecular Medicine, University College London

8:30 Tumour Specific Immunogene Therapy to Deliver Protein Therapeutics to Solid Tumour Microenvironments
Samantha Bailey-Bucktrout, PhD, Senior Vice President, Akamis Bio
The tumour-specific immunogene platform (T-SIGn) has been designed to deliver protein therapeutics selectively to tumor microenvironments following systemic dosing and is moving into Phase 2 clinical testing. Novel antibody fragments have been expressed and validated. The functionality of immune checkpoint inhibitors and immune inhibitors will be presented. Perspectives on the expression of combination therapeutics with fragment antibodies and other immune modulatory proteins within the solid tumour microenvironment will be discussed.

9:00 Local Secretion of Immune Active Proteins for Direct and Bystander Tumour Killing
Jonathan Fisher, PhD, Group Leader, University College London
Vg9Vd2-gdT cells are a versatile chassis for cellular immunotherapy, possessing potent antibody-dependent cellular cytotoxicity (ADCC) capacity, a tissue-tropic homing profile, and a range of innate tumour-sensing receptors minimizing the likelihood of tumour escape. OPS-gd is a cell therapy platform harnessing these properties, secreting tumour-targeting opsonins and armouring cytokines. OPS-gd cells show equivalent cytotoxicity but superior exhaustion phenotype to CAR-abT cells, engagement of ADCC-competent bystanders, and *in vivo* efficacy against patient-derived osteosarcoma.

9:30 Transgenic Llama Mice - a Fast and Flexible Single Domain Discovery Tool
Alessa Schaffrath, Doctoral Student, UKE Hamburg
Looking to rapidly generate a diverse pool of single-domain antibodies? Learn how Genovac partnered with UKE to establish a unique discovery platform combining Genovac's single cell screening tools with UKE's transgenic Llama mice, LaMice. UKE's transgenic LaMice are the latest addition to Genovac's class leading host species options which now includes transgenic and wild type mice and rats, rabbits, llamas and convalescent patient human cells.

10:00 Session Break to Transition into Plenary Keynote

PLENARY KEYNOTE SESSION

10:10 Plenary Keynote Introduction
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

10:15 Benchmarking the Impact of AI Biologics Discovery and Optimisation for Pharma
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca
At PEGS Europe, we will present current *in silico* biologics design and optimisation technologies, with a focus on our internal efforts to benchmark the impact of combining novel *in silico* technologies with our existing biologics discovery platforms.

10:45 Keynote Chat
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

10:45 Plenary Fireside Chat
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

11:00 Coffee Break in the Exhibit Hall with Poster Viewing

INNOVATIVE APPROACHES TO THE CHALLENGES OF SOLID TUMOURS

11:45 KEYNOTE PRESENTATION: AI-Based Target and Antibody Discovery from Patient Tumour Profiles
Xiaole Shirley Liu, PhD, CEO, GV20 Therapeutics
Patient tumours contain anti-tumour antibodies but might not have sufficient abundance and correct Fc to cure the tumours. GV20 uses bioinformatics and AI to decode natural B-cell responses from large cohorts of patient tumours to uncover novel targets and antibodies simultaneously. It already brought a first-in-class antibody against a novel innate checkpoint to Ph1 clinical trial in the US.

12:15 The Influence of DM1, MMAE, and MMAF on Biodistribution and Preclinical Therapeutic Efficacy of Affibody-Based Drug Conjugates
Torbjörn Gräslund, PhD, Professor, Department of Protein Science, KTH Royal Institute of Technology
Affibody molecules are small engineered alternative scaffold affinity proteins that can be site-specifically loaded with cytotoxic drugs to create homogenous conjugates with a desired drug-to-carrier ratio. The presentation will explore the targeting of HER2 and HER3 with affibody-based drug conjugates. It will also describe the impact on biodistribution and *in vivo* cytotoxic efficacy of drug conjugates loaded with auristatin and maytansine-derived payloads.

12:45 Cells meet biosensor – Automated determination of binding kinetics on living cells
Nena Matscheko, Dr., Team Lead R&D Cells and Antibodies, R&D, Dynamic Biosensors GmbH
Real-time binding kinetics are a pivotal element of drug candidate characterization. Dynamic Biosensors' innovative Real-Time Interaction Cytometry (RT-IC) technology enables automated time-resolved measurements of antibodies, small molecules, or proteins (e.g. pMHC) interacting directly with cells immobilized in the heliX^{cyto} biosensor. This renders cumbersome membrane protein purification superfluous and kinetic results (k_{on}, k_{off}, K_d) include effects of native co-interactions, avidity, and PTMs for highest relevance.

7TH ANNUAL | LISBON, PORTUGAL

EMERGING TARGETS AND THERAPEUTIC APPROACHES

Exploring Unconventional Approaches for Clinical Success in Oncology and Beyond

13:00 Presentation to be Announced

13:15 Session Break

13:20 LUNCHEON PRESENTATION I: Expression and Characterization of Novel GCN-Related N-acetyltransferases by Nuclera's Rapid Protein Access System

Hans Gerstmans, Postdoctoral Researcher, Laboratory for Biomolecular Discovery & Engineering, KU Leuven, VIB

Wai Long Tam, Head of Technology Watch at VIB, Technology Watch, VIB

GCN5-related N-acetyltransferases (GNATs) play a role in the acetylation of various proteins. GNATs are relevant to antibiotic resistance as integral enzymes that bacteria employ to modify antibiotics evading their effects and contributing to the development of resistance. Despite the importance of these enzymes, they have not been expressed and published on. Using Nuclera's eProtein Discovery system, we were able to find the expression conditions and obtain GNATs.

14:20 Session Break

14:30 Chairperson's Remarks

Kerry Chester, PhD, Professor, Molecular Medicine, University College London

14:35 Broadening Specificity of T-Cell Receptors for HLA-A*03:01/A*11:01 Alloselectivity

Vijaykumar Karuppiah, PhD, Associate Director, Protein Engineering, Immunocore

The recent approval of the first TCR-based drug represents an exciting advance for cancer immunotherapy. While HLA restriction may potentially limit patient coverage, this may be overcome when the same peptide antigen is presented on multiple HLA alleles. Here, we show that a TCR targeted towards a peptide presented by an HLA allele can be optimised by structure-guided mutations to also bind a second allele with similar affinity and potency.

ADVANCES IN DISCOVERY AND ENGINEERING OF ANTIBODIES FOR NON-CANCER TARGETS

15:05 Discovery of Broadly-Neutralizing Antibodies against Coronaviruses

Joshua Tan, PhD, Chief, Antibody Biology Unit, National Institute of Allergy and Infectious Diseases, National Institutes of Health

The potential for future coronavirus outbreaks and ongoing mutations in SARS-CoV-2 highlight the need to target this group of pathogens. We used an epitope-agnostic approach to identify two groups of monoclonal antibodies that target distinct regions of the spike protein and neutralize diverse coronaviruses. Our two-step approach of isolating rare neutralizing mAbs against cryptic targets is highly relevant for pandemic prevention and the development of therapeutic tools against emerging pathogens.

15:35 Antibody Discovery Dead Ends and New Approaches

Anthony Stajduhar, Director of Global Business Development, Business Development, Rapid Novor

Antibody discovery remains one of the most challenging aspects in antibody therapeutic development. Novel proteomics-based approaches to antibody discovery offers a promising strategy to overcome roadblocks often associated with other discovery technologies. With REpAb polyclonal sequencing, antibody discovery with mass spectrometry enables the exploration of the natural immune repertoire with unparalleled antibody diversity and creates a pathway for the discovery of novel human antibodies.

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 A Patient-First Approach to Discover First-in-Class Antibody Therapeutics

Jorge Dias, PhD, Principal Scientist, Alchemab Therapeutics Ltd.

Identifying genuinely novel targets that have immense therapeutic potential is an increasing challenge across central nervous system diseases. Alchemab addresses this challenge by truly disrupting the target discovery process — simply put, we let the patient select the best targets. We have discovered novel disease-relevant targets through our proprietary platform that searches for protective auto-antibodies in patients who are resistant to disease.

17:30 Advancing Snake Envenomation Treatment: Designing the Next Generation of Antivenoms

Sandra Ergueta-Carballo, PhD, Project Coordinator, University of Cambridge

Snake envenomation kills over 100,000 people annually and cripples three times as many. Current treatment relies on animal-derived serum, which, although life-saving presents many drawbacks, including lack of standardisation, a low proportion of neutralising antibodies, and serum sickness from injecting grams of animal protein. Therefore, it is crucial to modernise snakebite treatment. This presentation will show the ongoing efforts in developing the new generation of antivenoms and their associated challenges.

18:00 Advancing Brain Shuttle-Enabled Therapeutics for Efficient Delivery to CNS —Translation to Primates

Pawel Stocki, PhD, Vice President Research, Ossianix

We developed TXP1 brain shuttle based on anti-TfR1 antibody that can be fused to any therapeutic payload. In monkeys, TXP1 demonstrated ~35-fold improved brain penetration over the control, reaching up to 7.5% brain/plasma ratio. TXP1 showed to be safe and provided brain-specific delivery with no accumulation in other organs and had long-lasting brain PK, essential for efficacious CNS therapies.

18:30 Development of Autoregulating FVIII-Mimetic Bispecific Antibodies to Reduce Risk of Prothrombotic Events in Treatment of Haemophilia A

Vincent Muczynski, PhD, Director, NovalGen

Engineered proteins are powerful medicines, but may carry a risk of life-threatening toxicities. We have developed a broadly applicable approach of autoregulatable drugs by harnessing treatment-related biological signals to trigger inactivation of the drug at a set threshold through a negative feedback loop to prevent/attenuate high-grade adverse events. Using emicizumab, a marketed bispecific antibody for haemophilia A, we successfully demonstrated that autoregulation reduces frequency of thrombotic events.

19:00 Close of Emerging Targets and Therapeutic Approaches Conference

2ND ANNUAL | LISBON, PORTUGAL

ANTIBODIES AGAINST MEMBRANE PROTEIN TARGETS

R&D Strategies for GPCR, Ion Channel, and Transporter Targets

THURSDAY 16 NOVEMBER

7:30 Registration Open and Morning Coffee

DISCOVERY STRATEGIES

8:55 Chairperson's Remarks
Catherine Hutchings, PhD, Independent Consultant

9:00 KEYNOTE PRESENTATION: Selection Technologies for Membrane Targets Using Advances in Whole Cell Panning and Comparative Deep Sequencing
Benjamin J. Hackel, PhD, Professor, Chemical Engineering & Materials Science, University of Minnesota

Numerous, compelling molecular targets reside in the cellular membrane, which complicate discovery and engineering of binding ligands at library-scale. We have advanced yeast display technologies for membrane targets, including cellular panning, and comparative deep sequencing. We will present the development of these platforms, as well as case studies on their implementation in ligand discovery.

9:30 GPCR Production Strategies to Enable Antibody Discovery and Characterization
Keenan Taylor, PhD, Senior Scientist, AbbVie, Inc.

Recombinant production of GPCRs is challenging due to their complex structure and low stability outside of the lipid bilayer. Selection of the appropriate model membrane system and protein engineering strategy can address some of these challenges. Antigen formats, including virus-like-particles or polymer extracted membranes, must be carefully considered within the application context. In this talk, I will discuss GPCR antigen generation and purification, supporting antibody discovery and characterization efforts.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Structure-Function Studies of Salipro-CXCRs for Antibody Development
Jens Frauenfeld, PhD, Founder, CEO, Salipro Biotech AB

Membrane proteins are challenging drug targets (GPCRs, ion channels, transporters) and are notoriously difficult to work with. Our proprietary nano-membrane platform technology stabilises these important membrane proteins. We will present novel data on Salipro-CXCRs complexes, as well as case studies on other membrane protein types, to illustrate how the Salipro platform enables the development of next generation therapeutics (e.g. via SPR, phage display, B cell sorting and cryoEM.)

11:15 Stabilized GPCRs for Antibody Discovery
Jendrik Schöppe, PhD, Senior Scientist, Novo Nordisk

Generating monoclonal antibodies (mAbs) directed towards G protein-coupled receptors (GPCRs) poses many challenges, including antigen design, expression, and purification. In this presentation, I will share our experience using a stabilized, purified NK1 receptor as a soluble antigen in an *in vitro* selection campaign. Through this approach, we successfully identified mAbs that interact with the target: both on cells, and in surface plasmon resonance experiments.

11:45 Harnessing *in vivo* Diversities with a Yeast-Based Platform for the Discovery of Antibodies against Multi-Pass Membrane Proteins
Noel T. Pauli, PhD, Group Leader, Antibody Engineering, Adimab LLC

Integral membrane proteins continue to be a hurdle for antibody therapeutic discovery. By combining a yeast-based, single B cell platform with humanized transgenic murine diversities, we have developed a high-throughput methodology for the discovery of membrane-obligate-specific antibodies. In the absence of soluble recombinant antigen, this platform enables the discovery of large, clonally-diverse panels of high-affinity, target-specific antibodies.

12:15 Featured Poster Presentation: Conformation Locking scFvs for the Research and Discovery of FKBP51 Selective Ligands
Jorge A. Lerma Romero, Graduate Student, Biochemistry, Technical University of Darmstadt

The FK506-binding protein 51 (FKBP51) is a known target for stress and metabolic disorders. The high structural similarity between FKBP homologs represents a hurdle to designing selective ligands. We generated a yeast display library expressing chicken-derived scFvs and screened it via FACS to identify conformation-locking scFvs that stabilize the transient binding pocket of FKBP51. Conformation-locking scFvs may facilitate drug discovery of ligands selective to the FKBP51 transient binding pocket.

12:30 Enjoy Lunch on Your Own

13:50 Dessert Break in the Exhibit Hall & Last Chance for Poster Viewing

ROUNDTABLE BREAKOUT DISCUSSIONS

14:45 Roundtable Breakout Discussions

Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

TABLE 1: Membrane Protein Discovery Challenges
Noel T. Pauli, PhD, Group Leader, Antibody Engineering, Adimab LLC

TABLE 2: Characterization of Antibodies Against Membrane Proteins
Joseph Rucker, PhD, Vice President, Research and Development, Integral Molecular, Inc.

2ND ANNUAL | LISBON, PORTUGAL

ANTIBODIES AGAINST MEMBRANE PROTEIN TARGETS

R&D Strategies for GPCR, Ion Channel, and Transporter Targets

15:25 Session Break

BIOTHERAPEUTICS FOR MEMBRANE PROTEIN TARGETS

15:35 Chairperson's Remarks
Noel T. Pauli, PhD, Group Leader, Antibody Engineering, Adimab LLC

15:40 Strategies for Discovery of Functional Antibodies to Membrane Protein Targets
Trevor Wilkinson, PhD, Director, Biologics Engineering, AstraZeneca

Structurally complex membrane targets such as GPCRs, ion channels, and transporters are acknowledged as challenging targets for monoclonal antibody discovery. Strategies for discovery of functional antibodies to these target classes are emerging. This presentation will provide an overview of these emerging strategies and provide a number of case studies, including a new anti-GPCR antibody case study, highlighting the discovery and optimization of antibodies against GPCRs and ion channels.

16:10 Computer-Aided Design of Deimmunized Membrane Protein Ligands with Controlled Affinities
Savanna Skeeters, PhD, Scientist, Cyrus Biotechnology

Using computational methods that score physical features of protein structures or apply artificial intelligence approaches, homologs and *de novo* proteins are screened *in silico* to replace human signaling proteins and their receptors. Predicted HLA-II epitopes that pose immunogenicity risks are removed through targeted mutations, without damaging structure or activity. The proteins have a range of affinities, specificities, and signaling properties, which are tuned through experimental deep mutagenesis and affinity optimization.

16:40 ConfoBodies for Parallel Discovery of GPCR Agonistic Antibodies
Dorien De Vlieger, PhD, Scientist, Molecular Engineering, Confo Therapeutics

G protein coupled receptors (GPCRs) have a central role in many physiological processes, but are still underexplored (in many cases due to the absence of specific ligands.) Existing clinical stage GPCR drugs often result in treatment-limiting side effects, and could be replaced by therapeutic antibodies. We will show the unique potential of ConfoBody stabilized GPCRs to facilitate parallel discovery of highly-potent and selective (ant)agonistic biologics to peptide GPCRs.

17:10 Targeting Small Protein GPCRs by Engineering Their Natural Ligands
Oliver Hartley, PhD, Vice President, Drug Discovery, Orion Biotechnology

The GPCR superfamily contains a subset of approximately 50 receptors, whose natural ligands are small proteins. While these receptors are valuable drug targets linked to serious diseases, many remain undrugged because they present challenges to standard drug discovery approaches. This presentation describes Orion's novel solution to target small protein GPCRs: engineering the natural small protein ligand to discover potent analogs with enhanced binding properties and user-defined signaling activity.

17:40 Discovery and Characterization of Highly Potent Fc-Enhanced Anti-GPCR mAbs
Laura Mele, PhD, Investigator, GlaxoSmithKline

This talk will describe the discovery and biological characterisation of anti-GPCR mAbs. Antibodies against the target were obtained from a hybridoma discovery campaign. Clones selected for high cell binding potency and specificity to the target were engineered to enhance Fc effector function. We then identified Fc-enhanced clones displaying potent ADCC activity, in cells overexpressing and in cells endogenously expressing the target, as well as in primary target cells.

18:10 Close of Session

INAUGURAL | LISBON, PORTUGAL

SAFETY AND EFFICACY OF BISPECIFIC ANTIBODIES

Achieving Potent and Effective Bispecifics for Targeted Therapeutic Benefit

TUESDAY 14 NOVEMBER

7:30 Registration Open and Morning Coffee

RECENT ADVANCES IN BISPECIFICS, ADCs, AND COMBINATION THERAPIES

8:25 Chairperson's Remarks
Rakesh Dixit, PhD, President & CEO, Bionavigen

8:30 KEYNOTE PRESENTATION: Advances in the Efficacy and Safety of Bispecifics, ADCs, and Combination Cancer Therapies
Rakesh Dixit, PhD, President & CEO, Bionavigen
In the last decade, tremendous progress has been made to improve overall survival due to cancer and related illnesses. However, most cancers remain deadly, and therapeutic challenges are fierce. This keynote lecture will discuss the unprecedented progress in developing innovative bispecific, ADCs, and combination therapies in the war against cancers. A particular focus will be on the safety challenges of bispecific, immunotherapies, ADCs, and their combinations.

9:00 A Bispecific METxMET Antibody-Drug Conjugate with Cleavable Linker is Processed in Recycling and Late Endosomes
Andres Perez Bay, PhD, Senior Staff Scientist, Oncology & Angiogenesis, Regeneron Pharmaceuticals, Inc.
Most antibody-drug conjugates (ADCs) approved for the treatment of cancer contain protease-cleavable linkers. However, it remains unclear whether cleavable linkers can be processed outside the lysosomes. Here, we propose that recycling endosomes contributes to the processing of a bispecific METxMET ADC containing a VC-cleavable linker, and discuss the implications for the rational design of ADCs that recycle to the plasma membrane.

9:30 Next-Generation Cytokine Therapy: Coupling Dual Tumor Targeted Cytokines with Precision Patient Selection
John B. Mumm, PhD, Founder & CEO, Deka Biosciences
Deka Biosciences has in tandem developed a therapeutic platform (called Diakines) that couples complementary cytokines together via a tumor antigen targeting scaffold and a precision patient-selection method to provide the best therapy for each patient. The lead molecule, $DK2^{10}$ (EGFR), has for the first time uncoupled wild-type Interleukin-2 inflammatory toxicity from its potent anti-tumor function via coupling with nature's anti-inflammatory cytokine, Interleukin-10. Clinical trials with $DK2^{10}$ (EGFR) have begun.

10:00 POSTER HIGHLIGHT: MK-7240 (PRA023) Binds to Trimeric and Monomeric Soluble TL1A and Membrane TL1A
Johan Fransson, PhD, Executive Director, Antibody and Protein Therapeutics, Prometheus Biosciences
TL1A is a pro-inflammatory and pro-fibrotic protein expressed on antigen-presenting cells, endothelial cells, and also exists in soluble form as a cytokine in serum. Here we characterise the molecular mechanism-of-action of the TL1A antibody MK-7240 and show that both monomer and trimer forms of soluble TL1A exist in human serum, and that MK-7240 binds to both forms, in addition to binding and blocking the membrane-bound form of TL1A.

10:15 POSTER HIGHLIGHT: Manufacturability and Functionality Assessment of Different Formats of T-Cell Engaging Bispecific Antibodies
Han Ping Loh, PhD, Research Fellow, Cell Line Development, A STAR
In this study, we conducted a systematic comparison of eight different T-bsAb formats to understand how the molecular design of these antibodies affects their manufacturability and functionality. Our results showed that increasing scFv negatively impacted manufacturability, while functionality depended on various factors, including the format flexibility. Fab-FcK/scFv-FcH and Fab-FcK/FabscFv-FcH were identified as the optimal formats for developing Ig-like T-bsAbs.

10:30 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Targeting Alternative T Cell Effector Pathways to Enhance the Anti-Tumor Activity of CD3-Engaging Bispecific Antibodies
David J. DiLillo, PhD, Senior Director, Regeneron Pharmaceuticals, Inc.
CD3-engaging bispecific antibodies demonstrate strong anti-tumor activities in the clinic, but there is room to improve the efficacy and durability of these therapies. In this presentation, we will describe next-generation bispecific antibodies that engage T cell costimulatory pathways and discuss how they may be combined with CD3-engaging bispecifics to drive enhanced anti-tumor activity.

11:45 An Optimized IgG-Based B7-H3xCD3 Bispecific Antibody for Treatment of Gastrointestinal Cancers
Helmut R. Salih, MD, Professor for Translational Immunology, Medical Director, Clinical Collaboration Unit Translational Immunology, University Hospital Tuebingen and DKFZ Heidelberg, Germany; Co-Founder, TWYCE GmbH
In many malignancies, B7-H3/CD276 is expressed on both cancer cells and tumor vessels. The latter facilitates access of immune effector cells to the tumor site upon therapeutic targeting, a prerequisite for successful immunotherapy of solid tumors. We developed an optimized B7-H3xCD3 bispecific antibody with improved efficacy and reduced toxicity achieved by fine-tuning binding to both B7-H3 and CD3 that will undergo first-in-human testing in colorectal cancer in 2023.

12:15 Antibody Discovery Using the Galaxy® Library Platform RxBiologics
Phil Jones, VP Discovery, RxBiologics Ltd
Galaxy® is our proprietary technology platform. Our 'glass spleen' approach incorporates the learnings of the *in vivo* selection process and allows us to access a far greater fraction of relevant antibody space. Based on the principle of 'smart randomness', it harnesses the incredible diversity found within human B cells. Furthermore, the design provides the potential to rapidly generate cheap to manufacture bispecifics without the need for any special technology or engineering.

12:30 Presentation to be Announced

12:45 Session Break

12:55 LUNCHEON PRESENTATION I: Evaluation of Safety and Efficacy of antibody therapies in PBMC Humanized Mice The Jackson Laboratory
James Keck, PhD, President's Innovation Fellow and Senior Director, Innovation and Product Development, Product

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SAFETY AND EFFICACY OF BISPECIFIC ANTIBODIES

Achieving Potent and Effective Bispecifics for Targeted Therapeutic Benefit

Development, The Jackson Laboratory

A new approach is described for evaluating the potential toxicity of immunological therapeutics. Different variants of humanized mouse models predict candidate molecule efficacy and immunotoxicity to identify potential liabilities and define a therapeutic window for first-in-human trials. The system is reproducible, mirrors variable human response, and recapitulates the main clinical features of toxic events that escape the most common *in vitro* assays.

13:25 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

13:55 Session Break

14:05 PANEL DISCUSSION: Challenges of Mitigating Toxicity of IO Bispecifics

Moderator: Rakesh Dixit, PhD, President & CEO, Bionavigen

Panelists:

John B. Mumm, PhD, Founder & CEO, Deka Biosciences

David J. DiLillo, PhD, Senior Director, Regeneron Pharmaceuticals, Inc.

Helmut R. Salih, MD, Professor for Translational Immunology, Medical Director, Clinical Collaboration Unit Translational Immunology, University Hospital Tuebingen and DKFZ Heidelberg, Germany; Co-Founder, TWYCE GmbH

PRECLINICAL CONSIDERATIONS FOR SAFETY AND EFFICACY

14:35 Chairperson's Remarks

Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

14:40 Evolving Benefit-Risk Considerations for Bispecific Antibodies in an Era of Expanded Indications and Emerging Technologies

Christina Lourdes Mayer, PharmD, President & Principal Consultant, Semivida Research

This presentation explores the evolving landscape of benefit-risk considerations for bispecific antibodies amid expanded indications and emerging technologies. The relative safety and efficacy of bispecific antibodies compared with monospecific agents and alternative platforms will be discussed. Differences in benefit-risk for development of bispecific antibodies in different indications such as oncology and immunology will be examined. The impact of emerging technologies will be considered.

15:10 Bispecific Antibody Drug Conjugates for the Treatment of Acute Myeloid Leukemia — A Safer & More Efficacious Option for Patients?

Oliver Schon, PhD, Vice President, Research & Development, BiVictriX Therapeutics PLC

Gemtuzumab ozogamicin (GO) is the only ADC approved for use in CD33+ AML patients, but is associated with dose-limiting toxicities. The use of bispecific antibodies represents a novel approach to the development of ADCs with the potential of a more efficacious and safer treatment option for patients in the future. Here, we describe the twin antigen validation and target cell selectivity of an aCD7/aCD33 bispecific ADC.

15:40 Improved Understanding of Safety and Efficacy of Multifunctional Antibodies Using Circulating Whole Blood (ID.Flow) Immuneed.

Sakthi Srinivasan, PhD, Customer Project Lead, Business Science, Immuneed AB

Fresh human whole blood in circulation, with maintained cellular and protein composition, allows for improved understanding of drug-blood interactions. By using the ID.Flow system in your non-clinical work, cytokine release, complement and coagulation interactions as well as blood-based cellular binding patterns can be profiled in one assay, leading to improved pharmakokinetic and pharmacodynamic understandings of complex multifunctional antibodies prior First-In-Human (FIH) studies.

15:55 Presentation to be Announced

16:10 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Multispecific, Multivalent TSLP-IL13 NANOBODY

Annemie Deiteren, MD, PhD, Director, Translational Medicine & Clinical Pharmacology, Translational Medicine & Early Development, Sanofi

SAR443765 as a novel, anti-TSLP/anti-IL-13 Nanobody molecule significantly reduces FeNO, a biomarker of ongoing airway inflammation, in participants with asthma after a single dose. In addition, combined TSLP/IL-13 blockade improves lung function, particularly small airway dysfunction shown to correlate with poor disease control and type 2 inflammation. The effects surpass those reported for monovalent IL-13 or TSLP pathway targeting and suggest potential for superior effects in patients with asthma.

17:30 Strategies to Enhance Efficacy of a Tetraspecific Antibody to TNBC and PDAC

Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

The presentation highlights how TAVO412, a trispecific anti-cMET x anti-EGFR x anti-VEGF antibody has strong preclinical activity in triple negative breast cancer, gastric cancer, pancreatic cancer, and small cell lung cancer. A strategy of using combinations of standards of care treatments demonstrated stronger tumor growth inhibition. In addition, we highlight mechanisms of action of the engineering that contribute to solid tumor control.

18:00 PANEL DISCUSSION: Navigating Early-Stage Clinical Safety and Efficacy of Biologics for Acute Diseases Such as Oncology or Infectious Diseases

Moderator: Mark L. Chiu, PhD, CSO, Tavotek Biotherapeutics

There is continuing discovery and development of bispecific agents that can potentially treat diseases with unmet medical needs. Bispecific agent engineering requires the incorporation of several mechanisms-of-action for efficacy in the disease environment while controlling the engagement of on-target off-disease responses. This session will provide examples of the development of bispecific agents to optimize the therapeutic index by balancing potency and efficacy with safety for the patient.

Panelists:

Christina Lourdes Mayer, PharmD, President & Principal Consultant, Semivida Research

Oliver Schon, PhD, Vice President, Research & Development, BiVictriX Therapeutics PLC

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Safety and Efficacy of Bispecific Antibodies Conference

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ADVANCING BISPECIFICS AND COMBINATION THERAPY TO THE CLINIC

Novel and Synergistic Combinations

WEDNESDAY 15 NOVEMBER

7:30 Registration Open and Morning Coffee

TRANSLATIONAL APPROACHES TO OPTIMIZING DOSING

8:25 Chairperson's Opening Remarks
Paul Parren, PhD, CSO, Gyes; Professor, Molecular Immunology, Leiden University Medical Center

8:30 Bispecific Antibodies: Preclinical and Translational Strategies to Support Clinical Dose Setting
Esther C.W. Breij, PhD, Vice President, Head of Translational Research, Genmab BV

The presentation will review preclinical and translational strategies to help identify the optimal dose in the clinical setting. Examples will include preclinical pharmacodynamic studies for CD3 bispecific antibodies and immune agonist bispecific antibodies, as well as clinical biomarker studies to monitor pharmacodynamic activity of bispecific antibodies in the clinic.

9:00 KEYNOTE PRESENTATION: T Cell Redirecting Antibodies for the Treatment of Hematological Malignancies
Ulrike Philippar, PhD, Senior Director & Head, Oncology & Discovery Hematological Malignancies, Janssen Pharmaceutica NV

Within the past decade, therapies that activate T cells and redirect them to cancer cells have changed the landscape of treatment of hematological malignancies. Key factors for a successful T cell–redirecting therapeutic include selective target expression on the tumor cells, with minimal to no expression in other tissues, and a potent molecule, e.g.; a bispecific antibody, that can eliminate malignant cells to achieve long-term benefit.

9:30 TCER Development: Safety Aspects from Discovery to Lead Candidate
Fabian Richter, PhD, Immatics Biotechnologies GmbH

A robust safety profile plays a decisive role for clinical advancement. At Immatics "on-target off-tumor" and "off-target" reactivities are assessed throughout the entire TCER development process. During TCR identification and characterization, TCR stabilization and maturation and finally lead selection and IND preparation, reactivities towards target similar peptides, alternative allotypes and normal tissues are monitored closely to pave the way for further development into a safe and efficacious clinical product candidate.

10:00 Session Break to Transition into Plenary Keynote

PLENARY KEYNOTE SESSION

10:10 Plenary Keynote Introduction
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

10:15 Benchmarking the Impact of AI Biologics Discovery and Optimisation for Pharma
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

At PEGS Europe, we will present current *in silico* biologics design and optimisation technologies, with a focus on our internal efforts to benchmark the impact of combining novel *in silico* technologies with our existing biologics discovery platforms.

10:45 Keynote Chat
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

10:45 Plenary Fireside Chat
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

11:00 Coffee Break in the Exhibit Hall with Poster Viewing

T CELL ENGAGERS

11:44 Chairperson's Remarks
Nicolas Fischer, PhD, CEO, Light Chain Bioscience

11:45 ISB 2001: A First-in-Class Trispecific BCMA and CD38 T Cell Engager Designed to Overcome Mechanisms of Escape from Treatments for Multiple Myeloma by Targeting Two Antigens
Mario Perro, PhD, Vice President, Head of Oncology Research Department, Ichnos Sciences

ISB 2001 targets CD3 on T cells and co-targets BCMA and CD38 on Multiple Myeloma cells. Binding arms on ISB 2001 were derived from a synthetic phage display library using a common light chain. ISB 2001 exhibited higher killing potency (EC50) than all tested BCMA specific T cell engagers (TCE). *In vivo* tests with ISB 2001 show IgG-like half-life and efficient tumour eradication. Phase I trial is ongoing.

12:15 Bispecific Antibody Mediated, PD-L1-Dependant, CD28 Co-Stimulation
Sara Majocchi, PhD, Discovery Program Leader, Light Chain Bioscience – Novimmune SA

By associating a blocking anti-PD-L1 antibody arm with an agonist anti-CD28 antibody arm, we generated a PD-L1xCD28 bsAb (NI-3201) inducing CD28 signaling upon PD-L1 blockade on PD-L1+ tumor and immune cells (e.g., antigen-presenting cells). Data from the preclinical development of NI-3201 will be presented, with a focus on *in vitro* and *in vivo* de-risking activities.

12:45 Empowering Next-Gen Biologics with Industry Leading Fully Human Heavy Chain Only Antibody Platform at Nona Biosciences
Imran Clark, Ph.D., Associate Director, Business Development, Business Development, Nona Biosciences

Nona Biosciences' HCAb Harbour Mice® is the first fully human Heavy Chain only Antibody (HCAb) transgenic mice platform in history. It is optimized and clinically validated with global patent protection. HCAb Harbour Mice® efficiently produces high affinity and functional HCAbs with excellent biophysical characteristics. Fully human HCAbs are the ideal antibody format to generate a multitude of next-generation therapeutic modalities, including bispecific/multispecific antibodies, CAR-T, ADC, and mRNA therapeutics.

13:15 Session Break

NOVEL APPROACHES

13:20 LUNCHEON PRESENTATION I: Tailored CMC Solutions to Overcome The Challenges in

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ADVANCING BISPECIFICS AND COMBINATION THERAPY TO THE CLINIC

Novel and Synergistic Combinations

Bispecific, Fab and Fc-Fusion Protein Development Programs
Nicholas Field, Principal Scientist, Purification Development, Lonza
Lonza has applied 40 years of CMC experience in Biologics development to deliver a 14-month end-to-end DNA to IND strategy for Fc-fusion proteins and Fab fragments, as well as a 13-month offer for bispecific molecules. The integrated CMC strategy and timeline will be presented, as well as case studies highlighting key approaches and technologies, including: vector design & integration, cell line selection, downstream process, analytical method and formulation development. The capabilities and strategies that enable acceleration of Fc-fusion, Fab fragment and bispecific antibodies through pre-clinical development will be presented.

13:50 LUNCHEON PRESENTATION II: Heavy Chain-Only Transgenic Chickens Produce Human Antibodies with Robust Immune Repertoires and High-Affinity Binding
Phil Leighton, PhD, Senior Director, Molecular Biology, OmniAb
We have developed an engineered chicken that produces VHH antibodies with human variable regions. In these birds, the human VH contains framework mutations to provide stability and a truncated light chain that facilitates immunoglobulin secretion in the absence of the VL domain. Productive B-cell development is observed, and when immunized with various targets, antigen-specific VHH offered a diverse repertoire of sequences, broad epitope coverage, and binding affinities reaching single-digit nM.

14:20 Session Break

HARNESSING NEUTROPHILS USING BISPECIFICS

14:30 Chairperson's Remarks
Jeanette H.W. Leusen, PhD, Professor, Translational Immunology, Utrecht University

14:35 Bispecific IgA to Activate Neutrophils to Kill Cancer
Jeanette H.W. Leusen, PhD, Professor, Translational Immunology, Utrecht University
All current therapeutic monoclonal antibodies are based on IgG. For the past 25 years, we have been working on IgA as a different isotype to treat cancer, since it activates neutrophils very efficiently, even the suppressive type of neutrophils in the TME. At the moment, we are developing a bispecific antibody based on IgA, that also blocks CD47 as a myeloid checkpoint inhibitor molecule.

15:05 Neutrophil-Activating Therapy for the Treatment of Cancer
Thomas Valerius, MD, Professor, Stem Cell Transplantation & Immunotherapy, Christian Albrechts University of Kiel
Neutrophils (PMN) can constitute a numerically large fraction of the immune cell infiltrate in the TME, which often promotes tumor growth and invasiveness. However, PMN can also effectively kill tumor cells when they are properly activated. During this presentation recent data on the regulation of PMN's tumor cell killing activity by activating and inhibitory receptors will be presented.

15:35 Accelerating Early Discovery Through HTP and High-Speed Antibody Production
Lei Shi, PhD, Senior Vice President, R&D, Biointron Biological
Biointron has established an industry-leading 2-week antibody production service, supported by a powerful high-throughput expression platform. Armed with this high-efficiency platform, our FC-MES affinity maturation system is able to provide non-biased antibody optimization and affinity maturation in less than 2 months. Our VHH and Single B cell-based discovery projects are also benefited and expedited by this unique capability.

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

CO-STIMULATORY BISPECIFICS

16:59 Chairperson's Remarks
David E. Szymkowski, PhD, Vice President Preclinical Operations, Xencor, Inc.

17:00 Tumor-Targeted CD28 Bispecific Antibodies Preferentially Enhance T Cell Costimulation and Activation in the Tumor Microenvironment
David E. Szymkowski, PhD, Vice President Preclinical Operations, Xencor, Inc.
T cell costimulation enhances anti-tumor activity. However, solid tumors lack CD28 ligands. We hypothesized that tumor-associated-antigen x CD28 bispecifics could target costimulation in the microenvironment. Bispecifics against CEACAM5, mesothelin, STEAP-1, and Trop-2 enhanced T cell degranulation, cytokine secretion, and tumor-cell cytotoxicity, coupled with TCR engagement. To improve efficacy, we tuned bispecific formats and affinities to preferentially target cancer cells with high antigen expression. Such bispecifics warrant development for solid tumors.

17:30 CB307: A Novel T Cell Costimulatory Humabody VH Therapeutic for PSMA-Positive Tumours
Laurie Galson-Holt, PhD, Director Business Development, Crescendo Biologics Ltd
CB307 is a novel trispecific Humabody therapeutic targeting CD137, prostate specific membrane antigen (PSMA) and human serum albumin (HSA), enabling tumour-specific T cell activation, with minimal systemic activation. It is generated by formatting fully human VH domains from the Crescendo Mouse. CB307 mediates CD137 reporter cell signaling in PSMA dependent manner and enhances human T cells activity in co-culture assay. The first human clinical study (NCT04839991) is ongoing.

18:00 Tumor-Targeted Costimulation via CD28 Bispecific Antibodies: Turning Immunotherapy "Cold" Tumors "Hot"
Dimitris Skokos, PhD, Senior Director, Cancer Immunology, Regeneron Pharmaceuticals
We have recently described a class of costimulatory bispecifics that crosslink a tumor specific antigen to CD28 (e.g. PSMAxCD28, REGN5678), synergize with the broader anti–PD-1 approach, and endow responsiveness against tumors that otherwise do not respond to anti–PD-1 alone: such as, metastatic castration-resistant prostate cancer. By combining these bispecifics as off-the-shelf drugs, with aPD-1, we have the opportunity to create novel therapeutic synergies.

18:30 Two Targets, Two Signals: A Combinatorial Concept for Cancer Therapy with Bispecific Antibodies Directed to CD3 and CD28
Martin Pflügler, PhD, CEO, TWYCE GmbH
Success of bispecific antibodies (bsAbs) in solid tumors is still limited due to (i) lack of accessibility of the tumor site for immune effector cells, (ii) lack of sufficiently tumor-specific target antigens and (iii) lack of costimulatory "signal 2" that enables thorough and long-lasting T cell activation. Using our proprietary antibody platform, we overcome these limitations by combination of functionally interrelated bsAbs that target two different antigens on tumor cells

19:00 Close of Advancing Bispecific Antibodies and Combination Therapy to the Clinic Conference

14TH ANNUAL | LISBON, PORTUGAL

ENGINEERING BISPECIFIC ANTIBODIES

Designing New Antibody Therapies

THURSDAY 16 NOVEMBER

7:30 Registration Open and Morning Coffee

IMMUNOCYTOKINES

8:25 Chairperson's Remarks
Harald Kolmar, PhD, Professor and Head, Institute for Organic Chemistry and Biochemistry, Technische Universität Darmstadt

8:30 KEYNOTE PRESENTATION: Tripokin: Best-in-Class Potential for Tumor-Targeted Interleukin-2 (IL2) Potentiated by Tumor Necrosis Factor (TNF)
Roberto De Luca, PhD, Head, Therapeutic Antibodies, Philochem AG
A new potency-matched dual cytokine antibody fusion protein, named Tripokin, based on the L19 antibody (against EDB Fibronectin), was generated. Tripokin showed a favorable pharmacokinetic profile in monkeys, an excellent localization to neoplastic lesions in mice, and a potent anti-cancer activity in immunocompetent mouse models. The results provide a rationale for future clinical translation activities using Tripokin as a best-in-class potential tumor-targeted IL2 product.

9:00 PD1-IL18 IC (BPT567) — A First-in-Class and Highly Potent Immunocytokine Specifically Targeting of PD-1+/IL18R+/CD8+ T Effector Cells Enriched in the Tumor Microenvironment
Bertolt D. Kreft, PhD, CSO, Bright Peak Therapeutics
BPT567 is a PD1-IL18 immunocytokine harboring an engineered, optimized IL-18 payload. In cells expressing PD-1, BPT567 exhibits significantly enhanced potency due to *cis*-signaling. BPT567 induces the tumor-selective activation and expansion of $CD8^+$ T effector memory (Tem) cells and concomitant strong local IFNg release. $CD8^+$ Tem cell expansion translates into potent antitumor efficacy in multiple syngeneic mouse tumor models including models resistant to PD-1 inhibition.

9:30 Kinetic Antibody Characterization on Challenging Targets
Genedata
Dennis Verzijl, PhD, Principal Scientist, Genmab
Affinity is the strength of interaction between an antibody and its antigen. At Genmab, antibody affinities for soluble recombinant antigens are routinely measured using label-free technologies and analyzed using Genedata Screener. Soluble recombinant protein is usually not available for more challenging antigens such as proteins with multiple membrane-spanning domains. Here we show validation of in-house generated Virus-Like-Particles in combination with functionally monovalent bispecific antibodies to determine affinities for challenging targets.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

NOVEL APPROACHES AND FORMATS

10:44 Chairperson's Remarks
Harald Kolmar, PhD, Professor and Head, Institute for Organic Chemistry and Biochemistry, Technische Universität Darmstadt

10:45 Oncolytic Viral Vaccines: Platforms for Targeted Cancer Immunotherapy
Christine E. Engeland, MD, PhD, Researcher, Immunotherapy, German Cancer Research Center, DKFZ
Oncolytic viral vaccines are an emerging class of immunotherapeutics. As versatile engineering platforms, they can be harnessed for tumor-targeted delivery of bispecifics, checkpoint modulators, and cytokines. This talk will highlight recent preclinical developments and translational research in this field.

11:15 Creating and Targeting Cancer-Specific Neoantigens by Design
Shohei Koide, PhD, Professor, Biochemistry & Molecular Pharmacology, New York University School of Medicine; Perlmutter Cancer Center, NYU Langone Health
The HapImmune technology exploits small-molecule covalent inhibitors to create distinct neoantigens that selectively mark cells harboring an intracellular disease driver. We have developed antibodies that bind to FDA-approved KRAS(G12C) inhibitors conjugated to KRAS(G12C) peptides presented by HLAs, but not to the free inhibitors. Bispecific T cell engagers selectively kill inhibitor-resistant cancer cells upon inhibitor treatment. Our technology unites targeted and immune therapies, thereby expanding therapeutic opportunities against intracellular proteins.

11:45 Bispecific and Next-Generation Antibodies for Non-Oncology Indications Such as Ophthalmologic and Neurologic Diseases
Jens A. Fischer, PhD, Program Manager, Large Molecule Research Therapeutic Modalities, Roche Pharma Research and Early Development (pRED)
Biologics have revolutionized cancer treatment and impressive therapeutic effects of bispecific antibodies (BsAb) and Ig-fusion concepts resulted in approval in oncology and beyond. With great achievements in technical/clinical development of IgG-like BsAbs such as the Crossmab format, now smaller bispecifics like Dutafabs line up allowing combined inhibition of different pathological pathways in the eye and there is more progress and clinical evaluation of engineered large molecules in virology and neuroscience.

12:15 Accelerating Drug Discovery Using Advanced Antibody Development platformsAnnounced
Sino Biological
Yuchih Lin, Technical Specialist, Sino Biological Europe
Sino Biological's Antibodies Service is a game-changer in the field of biotechnology. With a reputation for excellence, we offer cutting-edge platforms for antibody development. Leveraging our expertise and state-of-the-art technology, we provide custom antibody services, including antibody humanization and therapeutic antibody discovery such as anti-idiotype, bispecific, and neutralizing antibodies. Sino Biological's commitment to innovation and precision makes us a vital partner in advancing antibody drug discovery.

12:30 DirectedLuck® for Bispecifics - A transposase System Streamlines Cell Line Development.
ProBioGen
Ellen Hilgenberg, PhD, Senior Business Development Manager, Business Development, ProBioGen AG
An elegant highly active transposase equipped with epigenetic readers carries expression units to most active spots in the host genome providing desired expression levels and stability. With this foundation the focus for screening producer clones is entirely on correct pairing and PTMs. We will discuss how this system is adapted to various formats and removing a critical bottleneck for bi-specifics during clinical development.

14TH ANNUAL | LISBON, PORTUGAL

ENGINEERING BISPECIFIC ANTIBODIES

Designing New Antibody Therapies

12:45 Session Break

12:50 LUNCHEON PRESENTATION I: Accelerating Bispecifics Discovery with the Alloy Common Light Chain Fully Human Transgenic Mouse Platform

Kent Bondensgaard, Ph.D., Senior Vice President of Antibody Discovery Service, Antibody Discovery Services, Alloy Therapeutics

Alloy bispecific discovery services integrates best-in-class platforms with world class scientists to serve as an extension of your R&D team. Building on industry leading mouse platforms for fully human antibody discovery, Alloy has created Common Light Chain strains, ATX-CLC, to build bispecifics with better developability profiles by solving heavy and light chain pairing. Leveraging ATX-CLC Alloy supports bispecific discovery through format engineering and functional assessment to move candidates forward rapidly.

13:20 LUNCHEON PRESENTATION II: Bispecific Antibody Engineering Integrated with AlivaMab® Platform to Deliver Selectively Functional Antibodies

Ankita Srivastava, PhD, Vice President, Antibody Engineering and Protein Sciences, AlivaMab Biologics

Multispecific antibodies have the potential to unlock novel biology and elicit unique functionalities. Antibody engineering strategies meeting therapeutic design goals and developability profiles for dual-antagonist and dual-agonist bispecific antibodies using both AlivaMab® antibodies and binders from other sources in IgG and non-IgG-like formats will be presented. These BiSAbs trigger function selectively only when bound to two target antigens simultaneously.

13:50 Dessert Break in the Exhibit Hall & Last Chance for Poster Viewing

NOVEL APPROACHES AND FORMATS (Cont.)

14:45 IgG-VHH Fusions: Technology-Driven

Steffen H.J. Goletz, PhD, Full Professor, Deputy Head, Vice Director, Biotechnology & Biomedicine, Danish Technical University

The talk will present comparison of formats for the generation of robust bispecific antibodies through fusion of single-domain antibodies on IgG scaffolds and complementary methods for in-depth analysis of key features, such as in-solution dual antigen binding, thermal stability, and aggregation propensity, to ensure high bsAb quality. It will present novel *in silico* designed humanized single-domain antibody phage display libraries with maximal functional diversity for generating fusion partners.

EFFECTOR CELL REDIRECTION

15:15 Chairperson's Remarks

G. Jonah Rainey, PhD, Senior Director, Protein Engineering, Eli Lilly and Company

15:20 elg-Based Bispecific T Cell-Engagers: Format Matters

Oliver Seifert, PhD, Senior Scientist, Institute of Cell Biology and Immunology, University of Stuttgart

The elg platform technology was used to generate a set of bispecific TCEs targeting EGFR and CD3. In total, 11 different TCE formats were analyzed for binding to target and T cells, T cell-mediated killing of tumor cells, and for the activation of T cells. Our findings support that screening of a panel of formats is beneficial to identify the most potent bispecific TCE, and that format matters.

15:50 TCER: Next-Generation, Half-Life Extended TCR Bispecifics Designed to Maximize Efficacy while Minimizing Toxicities for Patients

Felix Unverdorben, PhD, Associate Director, Immatics Biotechnologies GmbH

TCER are next-generation T cell receptor (TCR)-based T cell-engaging bispecifics targeting peptides presented by HLA-molecules on tumor cells. The use of a high-affinity TCR domain and a low-affinity T cell recruiter coupled to an Fc part for half-life extension has been shown in preclinical experiments to optimize efficacy, safety, and dosing schedule. Immatics is developing a broad pipeline of TCER addressing different indications and large patient populations.

16:20 Mastering Immunogenicity and Biologics Development

Jeremy Fry, Dr, Director of Sales, ProImmune

This talk explores the complexity of immunogenicity in drug design, emphasizing integrated platforms for biologic risk mitigation. Case studies demonstrate ProImmune's solutions: DC-T/T assays for lead optimization, MAPPS for antigen presentation, HLA-peptide assays for epitope characterization, and whole blood cytokine storm assays. Also introducing Ankyrons™, stable single-domain proteins revolutionizing target binding. Highly adaptable and easily engineered, they surpass current antibody limitations, offering a promising avenue in drug research.

16:50 ImmTAC: A High-Affinity Soluble TCR Bispecific Platform to Target Cancers

Christopher Rowley, PhD, Principal Research Scientist, Protein Science Pipeline, Immunocore

ImmTAC is a soluble TCR-antiCD3 bispecific targeting cancers. Tebentafusp is a first-in-class drug, approved to treat metastatic uveal melanoma. The TCR arm opens the possibility to target a large array of intracellular cancer antigens presented by cell surface MHC molecules. The platform is suitable to enhance TCR affinity by over a million-fold to target low levels of cancer antigens that are otherwise undetectable to the immune system.

17:20 gdT Cell Inspired Therapies

Jürgen Kuball, PhD, Head, Hematology, University Medical Center Utrecht

gdT cell inspired therapies gained substantial moment during the last decade resulting in multiple strategies for how to harness the anti-tumor potential of gdT cells for therapeutic concepts. I will discuss state-of-the-art in the context of current clinical data from most recent concepts as well as the potential future formats.

17:50 Activating NK Cell Receptors as Trigger Molecules for Bispecific Antibodies to Enhance Anti-Tumor NK Cell Responses

Matthias Peipp, PhD, Research Head & Mildred Scheel Professor, Stem Cell Transplantation & Immunotherapy, University of Kiel

Bispecific antibodies engaging NKG2D or NKp30 and binding a tumor-associated antigen were generated to sensitize tumor cells to NK cell-mediated killing. The impact of molecular architecture on cytotoxic activity and the capacity to act as co-stimulators for FcgRIIIa-triggered anti-tumor responses will be discussed. This approach may represent a promising strategy to modulate stronger NK cell-mediated antitumor responses and to boost the activity of therapeutic antibodies.

18:40 Close of PEGS Europe Summit

6TH ANNUAL | LISBON, PORTUGAL

MODULATING THE TUMOUR MICROENVIRONMENT

Overcoming Immune Suppression and Activating Tumour Response

TUESDAY 14 NOVEMBER

7:30 Registration Open and Morning Coffee

MODULATING ANTIBODY RESPONSES AND ENHANCING ANTI-TUMOUR ACTIVITY

8:25 Chairperson's Remarks
Björn L. Frendeus, PhD, CSO, BioInvent International AB

8:30 Modulating Antibody Effector Functions in the Tumour Microenvironment
Mark S. Cragg, PhD, Professor of Experimental Cancer Biology, Antibody and Vaccine Group, School of Cancer Sciences, University of Southampton

There is growing appreciation of the depth of interaction between tumour cells and their microenvironment which modulates tumour growth, proliferation and immune suppression. The impact of these interactions on antibody immunotherapy is poorly defined. This presentation will discuss several key interactions between the host and the tumour in different anatomical niches that impact different types of antibody immunotherapy and how they might be targeted to improve treatment efficacy.

9:00 Modulation of B Cell and Antibody Responses in Solid Tumors
Sophia N. Karagiannis, PhD, Professor, Translational Cancer Immunology & Immunotherapy, Kings College London

We report B cell class-switching to less immunoactive antibody isotypes and regulatory cytokine-expressing B cell subsets, promoted in alternatively-activated Th2-biased conditions in tumors. These form part of an anti-inflammatory environment associated with less favourable outcomes. Skewed B cell and immunoglobulin profiles reveal novel prognostic biomarkers, and point to opportunities for the development of antibody immunotherapies less prone to tumor-associated immunosuppressive forces.

9:30 ANV600, a Uniquely Engineered, cis-Signaling IL-2R b/g Agonist, Efficiently Expands Intratumoral Stem-Like and Effector CD8 T Cells
Patrizia Murer, PhD, Head, Protein Engineering, Anaveon AG

ANV600, a novel bispecific featuring an anti-IL-2 antibody/IL-2 fusion protein and a PD-1 binding moiety for targeted delivery of the IL-2R b/g-directed IL-2 to tumor antigen experienced PD-1+ T cells. The IL-2 is embedded in the antibody CDR-L1, thereby excluding the IL-2Ra from binding to the cytokine. ANV600 has potent and selective proliferating effects on stem-like and effector CD8 T cells and markedly inhibits tumor growth in mouse tumor models.

10:00 POSTER HIGHLIGHT: Turning the Tumor Hot: Genetically Engineered Macrophages to Disrupt the Cold Tumor Microenvironment
Simon Bredl, PhD, Sr Scientist, Infectious Diseases & Hospital Epidemiology, Univ Hospital Zurich

Immunotherapies struggle in solid, so-called "cold" tumors due to the immunosuppressive tumor microenvironment (TME). M2-like tumor-associated macrophages (TAM) aid tumor growth and support the establishment of the TME. In contrast, M1 TAM shows promise in treating such tumors. We have successfully genetically modified macrophages with a chimeric cytokine receptor (ChCR), which induces a M1-like activation of the macrophages with tumoricidal properties when exposed to the M2-inducing cytokines IL-10 or TGFβ.

10:15 POSTER HIGHLIGHT: Deciphering The Structural Details of The Recognition Mode of Cancer-Associated Glycoproteins By Siglec Receptors Implicated in Immune Suppression in Cancer
Klaudia Sobczak, Early Stage Researcher, Chemical Glycobiology Lab, CIC bioGUNE

Siglecs are receptors expressed on immune cells that recognise sialic acid-containing glycans. Siglec-sialic acid axis regulates the immune responses and participates in tolerance to "self"-antigens in conditions like sepsis, autoimmune diseases, and cancer. Our research is focused on studying the interactions at the molecular level between Siglecs and their ligands to translate this knowledge into the development of novel therapeutics (either based in antibodies or modified glycans).

10:30 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:15 PD-1-cis IL-2R Agonism Yields Better Effectors from Stem-Like CD8+ T cells
Laura Codarri Deak, PhD, Senior Principal Scientist, Cancer Immunotherapy, Roche Innovation Center, Zurich

Recent reports have demonstrated that a population of tumor-specific T cells (Tstem-like) is critical for the response to anti-PD1 therapy. Interleukin-2 has been described to induce the differentiation of Tstem-like towards functional effectors. Unfortunately, IL-2 is toxic and detrimentally expands regulatory T cells. We developed PD1-IL2v, an immune cell-targeted IL-2v to promote an effective and long-term anti-tumor immune-response by expanding a novel CD8 T cell population, derived from Tstem-like.

11:45 Improving Cytokine Therapy Efficacy and Safety by Using Combination Agents Targeted to the Tumor Microenvironment
John B. Mumm, PhD, Founder & CEO, Deka Biosciences

Deka Biosciences has developed a platform to produce novel combination cytokine therapies aiming to mitigate known toxicity risks, while maintaining the anti-tumor function. Using targeting binding scaffolds facilitates fast uptake in the tumor microenvironment and reduces drug-antibody formation and systemic cytokine release syndrome. The unique configuration Deka's Diakines create a new generation of far more stable cytokine therapy which can be given 3-times/week subcutaneously.

12:15 A Novel TCR-specific Engager Platform (Immuno-STAT) Enabling Next Generation Approaches to Targeted Immunotherapies
Simon Low, PhD, Sr Dir, Biologics Discovery & Innovation, Cue Biopharma

Immuno-STATs are Fc fusion molecules that can simultaneously engage, activate, and expand existing disease-specific T-cells to induce cancer cell destruction. Lead clinical candidate, CUE-101, targets HPV E7-specific T cells and demonstrates efficacy in late-stage head and neck cancer patients. With this clinical proof-of-concept and platform de-risking, we present our Immuno-STAT platform; its adaptability to target additional tumor types and modularity to expand potential of patient reach and diversity.

12:45 Attend a Sponsored Presentation or Enjoy Lunch on your own

6TH ANNUAL | LISBON, PORTUGAL

MODULATING THE TUMOUR MICROENVIRONMENT

Overcoming Immune Suppression and Activating Tumour Response

TARGETING MYELOID CELLS

14:05 Chairperson's Opening Remarks
Stephen A. Beers, PhD, Professor of Immunology & Immunotherapy, University of Southampton

14:10 KEYNOTE PRESENTATION: Perivascular Macrophages as a Therapeutic Target in Potentiating the Immune-Stimulatory Effects of Chemotherapy against Cancer
James N. Arnold, PhD, Reader, Tumor Immunology, Kings College London
We describe and characterise a subset of tumour-associated macrophages (TAMs) identified by their expression of LYVE-1 and HO-1 which reside in CCR5-dependent nests proximal to blood vasculature in cancer. Depletion approaches for this subset slow tumour growth in a spontaneous murine model of breast cancer. Our data highlight that this subset is associated with the immunological 'heat' and immune suppression in the tumour which influences the effectiveness of chemotherapy.

14:40 Novel FcαRI Bispecific Antibody Immunocytokines for the Recruitment of Myeloid Effector Cells in Cancer Therapy
Marjolein van Egmond, PhD, Professor, Oncology and Inflammation, Surgery/Molecular Cell Biology and Immunology, Amsterdam UMC
This presentation introduces innovative bispecific antibody immunocytokines targeting FcαRI, to enhance cancer therapy by recruiting myeloid effector cells to the tumor microenvironment, as a potential promising immunotherapeutic approach.

15:10 IL-2 Promotes Antitumor Responses via a Lymphoid-Dendritic Cell Pathway
Miro E. Raeber, MD, PhD, Assistant Professor for Clinical Immunology, Faculty of Medicine, University of Zurich, Department of Immunology, University Hospital Zurich
Tumor-infiltrating dendritic cells (DC) correlate with effective anti-cancer immunity and improved responsiveness to anti-PD-1 checkpoint immunotherapy. However, the upstream drivers of DC expansion and intratumoral accumulation are ill-defined. We find that interleukin-2-mediated, innate, and adaptive lymphoid cell-driven DC-poiesis in mice and humans resulted in pronounced expansion of type-1 and type-2 DCs with improved antigen presenting properties, which correlated with favorable anti-cancer responses.

15:40 POSTER HIGHLIGHT: Promoting Immune Response of Endothelial Cells by Bevacizumab: Insights into the Role of Anti-VEGF Therapy in Reprograming the Immunosuppressive Tumour Microenvironment
Haiyan Jia, PhD, Principal Scientist, Biotherapeutics & Advanced Therapies, MHRA
We investigated the impact of Bevacizumab, anti-VEGF monoclonal antibody on endothelial cell immune response and found that Bevacizumab treatment of HUVECs enhanced TNFa stimulation of surface expression of adhesion molecules E-selectin, ICAM-1 and VCAM-1, and promoted IFNγ and TNFa upregulation and reversed VEGF downregulation of MHC Class I expression, indicating that anti-VEGF treatment can support the immune response of ECs in directing immune cell trafficking and recruitment of CD8 Tcells.

15:55 POSTER HIGHLIGHT: Empowering GITR-Targeted Agonistic Antibody-Based Immunotherapy by Fc Engineering
Yahel Avraham, Graduate Student, Systems Immunology, Weizmann Institute Of Science
Alternative therapeutic approaches use agonistic antibodies to target immune stimulatory receptors, such as GITR. Here, we elucidated the role of hFcgRs in the activity of GITR mAbs. By utilizing a mouse model that recapitulates human FcgRs expression, we identified novel FcgR-dependent mechanisms of GITR targeting that shift T cell ratios within the tumor. We developed novel IgG scaffolds of GITR mAbs that harness these mechanisms to increase the therapeutic efficacy.

16:10 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 The Modular PreTargit Platform Enables RIT for Hard-to-Treat Cancers by Significantly Improved Therapeutic Indexes
Alexander Schinagl, PhD, Founder & CTO, OncoOne R&D GmbH
cON-05 is a bispecific antibody comprising an arm binding to HSG (histamine-succinyl-glycine) and a Fab directed against oxMIF, the disease-specific conformational isoform of MIF (macrophage migration inhibitory factor). A two-step pretargeted radioimmunotherapy with cON-05 and a [177]Lu-labeled di-HSG peptide was tested in murine models of cancer. The treatment was well tolerated and led to significant tumor regression in colorectal cancer syngrafts and tumor growth inhibition in pancreatic cancer xenografts.

17:30 FcgR Blockade to Enhance Cancer Immunotherapy
Björn L. Frendeus, PhD, CSO, BioInvent International AB
The inhibitory immune checkpoint FcgRIIB promotes resistance to antibody therapy acting on tumour and myeloid effector cells. We have developed function-blocking antibodies to FcgRIIB with differentiated mechanisms-of-action (BI-1206 and BI-1607). This talk will discuss how tailored FcgR blockade enhances anti-CD20, anti-Her2, anti-PD-1/L1, and anti-CTLA-4 therapeutic activity, and how it may help overcome antibody drug resistance and bring clinical benefit of immune checkpoint blockade to patients with poorly T cell-infiltrated tumours.

18:00 Preclinical Discovery of ARX622, a Site-Specific HER2-Targeted TLR7 Agonist Immune-Stimulatory Antibody Conjugate
David Mills, PhD, Senior Director, Preclinical Science, Ambrx, Inc.
This presentation highlights the preclinical discovery of ARX622, a site-specific HER2-targeted TLR7 agonist ADC with stable conjugation, efficacy in large established tumor models, and a wide therapeutic index based on preclinical exposure data.

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Modulating the Tumour Microenvironment Conference

6TH ANNUAL | LISBON, PORTUGAL

INNOVATIONS IN CAR T THERAPY AND ENGINEERING *IN VIVO* SOLUTIONS

Improving Access and Overcoming Challenges

WEDNESDAY 15 NOVEMBER

7:30 Registration Open and Morning Coffee

OVERCOMING THE TUMOUR MICROENVIRONMENT

8:25 Chairperson's Opening Remarks
Astero Klampatsa, PhD, Team Leader, Cancer Therapeutics, Institute of Cancer Research

8:30 Strategies to Overcome CAR T Cell Suppression in the Tumor Microenvironment
Sebastian Kobold, MD, Professor, Clinical Pharmacology, Klinikum der Universität München
A major hurdle to CAR T cell efficacy in solid tumors is their suppression by both cancer cells and their environmental surroundings. In this talk, we will demonstrate how CAR T cell activity can be boosted by modulating both TME and tumor-derived or associated factors.

9:00 Co-Engineering Strategies to Augment T Cell Control of Solid Tumors
Melita B. Irving, PhD, Project Leader, Ludwig Branch for Cancer Research, University of Lausanne
T cell therapies of solid tumors face challenges including limited homing, antigen escape, immunosuppression, and toxicity. Coengineering strategies can circumvent many of these obstacles. To that end, we developed a dual inverted lentiviral vector enabling constitutive expression of a TCR or CAR and activation-inducible gene-cargo. We have also built remote-control CARs and explored a variety of gene-cargo including IL-15, IL-2v, GLUT3, and a SiRPa decoy to safely augment tumor control.

9:30 Optimizing CD4+ T Cells Long-term Expansion Process in Stirred-tank Bioreactors: Impact of the Dissolved Oxygen eppendorf
Françoise de Longueville, Dr., Managing Director / Head of Core Test Lab, Eppendorf Application Technologies S.A.
T cell lymphocytes play a central role in the adaptive immune response and are an essential tool of cell therapies.The development of cell-based therapies requires the production of a large quantity of high-quality viable T cells.Stirred-tank bioreactors offer a homogeneous environment for the controlled cultivation of T cells.Here,we tested the suitability of Single-Use Bioreactors for the long-term expansion of CD4+ T cells and the impact of oxygen tensions on cell proliferation.

9:45 Talk Title to be Announced KACTUS
Speaker to be Announced

10:00 Session Break to Transition into Plenary Keynote

PLENARY KEYNOTE SESSION

10:10 Plenary Keynote Introduction
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

10:15 Benchmarking the Impact of AI Biologics Discovery and Optimisation for Pharma
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca
At PEGS Europe, we will present current *in silico* biologics design and optimisation technologies, with a focus on our internal efforts to benchmark the impact of combining novel *in silico* technologies with our existing biologics discovery platforms.

10:45 Keynote Chat
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

10:45 Plenary Fireside Chat
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

11:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:45 New T Cell Engineering Approaches for Mitigation of Exhaustion and Targeting of Low Antigen Density
John Anderson, PhD, GOSHCC Professor, Honorary Consultant Oncologist, Experimental Paediatric Oncology, University College London
CAR T therapies for solid cancers have proven susceptible to T cell exhaustion and antigen escape, leading to relative clinical failure. We have focused on commonly expressed antigen B7H3, and have developed CARs based on high-avidity binders capable of response to antigen-dim targets. To mitigate exhaustion caused by chronic signaling we have developed IMiD drug-sensitive degron sequences that control rapid and reversible receptor proteosomal degradation, which can reverse antigen-induced exhaustion.

12:15 Overcoming Tumor Antigen Heterogeneity in the Context of CAR T Cell Therapy for Solid Tumors
Astero Klampatsa, PhD, Team Leader, Cancer Therapeutics, Institute of Cancer Research
A study is discussed looking into the limitations in efficiency of CAR T cell therapy in an antigen-heterogeneous syngeneic tumor model and whether this can be overcome by CAR T cell induction of bystander effects.

12:45 Enjoy Lunch on Your Own

IN VIVO DEVELOPMENTS AND DELIVERY USING LNPs AND mRNA

14:30 Chairperson's Remarks
Ulf Grawunder, PhD, CEO & Co-Founder, T-CURX

6TH ANNUAL | LISBON, PORTUGAL

INNOVATIONS IN CAR T THERAPY AND ENGINEERING *IN VIVO* SOLUTIONS

Improving Access and Overcoming Challenges

14:35 T Cell-Specific *in vivo* CAR-Delivery by Receptor-Targeted Viral Vectors
Frederic B. Thalheimer, PhD, Molecular Biotechnology & Gene Therapy, Paul Ehrlich Institut
CAR T cells have proven their tremendous potential to cure hematologic malignancies. However, their highly individualized, expensive, and time-consuming manufacturing make broader applications difficult. Towards converting the strategy to an off-the-shelf approach, we generated receptor-targeted lentiviral and AAV vectors redirected to T cells for direct *in vivo* generation of CAR T cells.

15:05 Viral Vectors for Highly Specific Immunoengineering of B and T Cells *in Situ*
Samuel Lai, PhD, Professor, Pharmacoengineering & Molecular Pharmaceutics, University of North Carolina at Chapel Hill
A platform that can selectively transduce specific immune cells *in vivo* can enable a range of personalized cellular and biologics immunotherapy. Towards this goal, our group has employed various principles from molecular biology and pharmaceutics to engineer different viral vector systems that can selectively transduce B and T cells *in vivo* with exceptional fidelity and potency. We will present both published and unpublished data.

15:35 Session Break

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

OPTIMISING CARs

16:59 Chairperson's Remarks
Ulf Grawunder, PhD, CEO & Co-Founder, T-CURX

17:00 KEYNOTE PRESENTATION: New Targets and Technologies for CAR T Cells
Michael Hudecek, MD, Professor, Cellular Immunotherapy of Malignant Diseases, University of Wuerzburg
This talk will provide an update on our ongoing effort to improve CAR design, immune cell subset composition, and the fitness of immune cells in order to improve efficacy while maintaining safety and tolerability of CAR therapy.

17:30 High-Throughput Screening to Enable the Selection of a Multi-Feature, Logic-Gated CAR T Cell Candidate
Angela C. Boroughs, PhD, Associate Director, Immunology, ArsenalBio
CAR T cells likely require enhancements to be clinically effective against solid tumors. We have identified multiple features for integration into T cells to increase tumor specificity and potency. However, combining multiple features may result in unpredictable interactions between components such as the receptor's single-chain variable fragments. Here we describe high-throughput screening to select optimized receptor combinations in highly engineered integrated circuit T cells for the treatment of kidney cancer.

18:00 Improving Cell Therapies with High-Throughput CAR Libraries
Chad May, PhD, CSO, Serotiny, Inc.
Despite clinical success with cell therapies targeting hematological malignancies, achieving a safe and persistent efficacious dose in patients with solid tumors remains a challenge. Serotiny's high-throughput platform is built to engineer next-generation multi-domain protein designs, including chimeric antigen receptors (CARs), that overcome these challenges. Serotiny has demonstrated the use of its high-throughput platform to build and deliver CARs that improve *in vivo* responses in preclinical studies.

18:30 PANEL DISCUSSION: WHAT IS THE NEXT GAME CHANGER IN THE CAR T CELL FIELD?
Co-Moderators:
Ulf Grawunder, PhD, CEO & Co-Founder, T-CURX
Astero Klampatsa, PhD, Team Leader, Cancer Therapeutics, Institute of Cancer Research
- *In vivo* CAR T cells
- Solid tumor targeting
- Myriad constructs and atypical CARs, non-antibody designs
- Scalability and engineering advances, allogeneic CAR T approaches

Panelists:
John Anderson, PhD, GOSHCC Professor, Honorary Consultant Oncologist, Experimental Paediatric Oncology, University College London
Michael Hudecek, MD, Professor, Cellular Immunotherapy of Malignant Diseases, University of Wuerzburg
Sebastian Kobold, MD, Professor, Clinical Pharmacology, Klinikum der Universität München

19:00 Close of Innovations in CAR T Therapy and Engineering *in vivo* Solutions Conference

INAUGURAL | LISBON, PORTUGAL

NEXT-GENERATION IMMUNOTHERAPIES

Improving Immunotherapy Safety & Efficacy

THURSDAY 16 NOVEMBER

7:30 Registration Open and Morning Coffee

8:25 Chairperson's Remarks
Daniel Chen, MD, PhD, Founder, Engenuity Life Sciences

8:30 KEYNOTE PRESENTATION: An Unexpected Future for Immune Oncology Therapies?
Bent Jakobsen, PhD, FMedSci, CEO & Founder, Accession Therapeutics Ltd.
Checkpoint inhibitors and multiple forms of antigen-targeted stimulators have demonstrated that the immune system can be harnessed against both liquid and solid cancer types; the potential for future developments seems huge. The field faces three challenges: a shortage of targets, tumor defense mechanisms and, perhaps the worst, the huge diversity of cancer cells. The solution to generating immune therapies that can control cancers may require some unexpected and counter-intuitive approaches.

CELL-BASED IMMUNOTHERAPIES

9:00 Reprogramming CAR T Cells *in vivo* Using Targeted LNPs
Viktor Lemgart, PhD, Research Fellow, Tidal Therapeutics, a Sanofi Company
CAR T cell therapies have proven successful in the clinic, but their broad application is still facing significant challenges due to the elaborate and expensive engineering and manufacturing of cells. Sanofi has developed a new technology that allows the generation of CAR T cells directly *in vivo*. The technology uses mRNA, formulated in LNPs that are specifically targeted to circulating T cells to transiently express CARs on the surface.

9:30 Targeting TAAs to Fight Cancers: Choice between TCE and ADC
WuXi Biologics Global Solution Provider
Yunying Chen, Vice President, Biologics Innovation & Discovery (BID), WuXi Biologics
Targeting TAA with TCE and/or ADC has emerged as the two powerful immunotherapeutic modalities to fight cancers. We are developing leading immune cell-engaging platforms and building ADC capabilities to enable our clients to discover novel therapeutics. We will discuss our insights to assess TAAs and considerations on how to match TAAs with the right technologies to maximize the clinical efficacy and minimize the safety risk of a TCE or ADC molecule.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Novel Concepts to Regulate CAR T Cell Activity with Small Molecule Drugs *in Vivo*
Michael Traxlmayr, PhD, Group leader, CD Laboratory for Next-Generation CAR T Cells, University of Natural Resources & Life Sciences
CAR T cells can proliferate and persist in patients for several years. However, this remarkable feature comes with a drawback: once administered, it is challenging to control their activity. To address this limitation, we have engineered molecular switches, enabling regulation of CAR T cell activity with small molecule drugs. As an alternative strategy, we developed AvidCARs, which enable both combinatorial antigen recognition and drug-mediated control of CAR T cell function.

11:15 Novel scFv against Notch Ligand JAG1 Suitable for Development of Cell Therapies toward JAG1-Positive Tumours
Gabriela de Medeiros Silva, PhD, Research Investigator, Animal Cell Technology, iBET Instituto de Biologia Experimental Tecnologica
The Notch-signaling ligand JAG1 is a key oncogene involved in aggressive solid tumors correlated with poor clinical prognosis. Here we report novel anti-JAG1 scFvs that specifically recognize JAG1 in the Ab format and show that one molecule enables CAR T cells to specifically recognize JAG1-expressing cells promoting their killing. These findings suggest this new anti-JAG1 scFv might be a good candidate for the development of cell therapies targeting JAG1-positive tumors.

11:45 SYNCAR: Engineered Human IL-2/IL-2Rβ Orthogonal Pairs That Selectively Enhance CAR T Cell Anti-Tumor Efficacy in Liquid and Solid Tumor Models
Paul-Joseph P. Aspuria, PhD, Director, Cell Therapy, Cell Therapy, Synthekine, Inc.
This talk will present the innovative SYNCAR technology which leverages engineered IL-2/IL-2Rß orthogonal pairs to selectively enhance the anti-tumor efficacy of CAR T cells, addressing challenges faced in both liquid and solid tumor models.

12:15 Sponsored Presentation *(Opportunity Available)*

12:30 Droplet Based Flowcytometry for Function-based Screening of Single Immune Cells in Xdrop DE50 Droplets
Samplix
Bárbara Schlicht, Head of Product Management, Commercial Operations, Samplix
Xdrop DE50 droplet preparation is fast, Flowcytometry compatible and ideal for high-throughput single cell screening
Functional screening of single immune cells in Xdrop DE50 droplets accelerates antibody screening workflows
Cell–cell interaction and cytokine secretion assays in Xdrop DE50 droplets contribute to improved cell therapy development

12:45 Session Break

12:50 LUNCHEON PRESENTATION I: Specificity Testing of Antibodies, Bispecifics, and CAR T Therapeutics for IND Using the Membrane Proteome Array
integral molecular
Rachel Fong, Director of Sales and Alliances, Integral Molecular
Assessment of off-target antibody reactivity is a regulatory requirement for clinical development. However, conventional screening methods are often ineffective in screening newer therapeutic modalities, including cell therapies. We will present the Membrane Proteome Array (MPA): a 6,000-protein cell-array for specificity screening, case studies describing its successful use for regulatory filings, and the status of the MPA being developed as a qualified Drug Development Tool under consideration by the FDA.

13:20 LUNCHEON PRESENTATION II: Rapidly Assemble Genes in Your Laboratory Using Automated Enzymatic Oligo Synthesis
DNASCRIPT

INAUGURAL | LISBON, PORTUGAL

NEXT-GENERATION IMMUNOTHERAPIES

Improving Immunotherapy Safety & Efficacy

Steven Quistad, PhD, Senior Applications Scientist, DNA Script

To demonstrate the utility of the SYNTAX system in gene assembly the 1.7 kb Influenza A hemagglutinin gene was used as a model system. Three double stranded DNA (dsDNA) blocks were generated from EDS-synthesized ssDNA oligos using the PCA approach followed by error correction. The dsDNA blocks were then assembled using a commercially available kit, transformed into BL21 competent cells and colonies were selected for Sanger Sequencing confirmation.

13:50 Dessert Break in the Exhibit Hall & Last Chance for Poster Viewing

VACCINES

14:35 Chairperson's Remarks

Viktor Lemgart, PhD, Research Fellow, Tidal Therapeutics, a Sanofi Company

14:40 Neoepitopes Cancer Vaccine Monotherapy Positive Efficacy in Non-Small Cell Lung Cancer with Resistance to Immunotherapy Randomized Phase 3

Nicolas Poirier, PhD, CSO, OSE Immunotherapeutics

Tedopi is a subcutaneous cancer vaccine based on highly-selected and optimized tumor neoepitopes which activates and expands tumor-specific CD8 T lymphocytes. We recently reported positive clinical efficacy of Tedopi versus chemotherapy in a randomized Phase III trial in Non-Small Cell Lung Cancer in patients with secondary resistance after failure of checkpoint inhibitors, with significantly better survival, safety profile, and quality of life based on several patient-related outcomes.

15:10 The New Age of Immunotherapy: From Checkpoint Inhibitors to Vaccines

Nageatte Ibrahim, MD, Vice President, Oncology & Global Clinical Development, MSD

In this presentation, I will discuss the newer checkpoint inhibitors as well as current data from different vaccine platforms studies available to date, and give an update on the melanoma phase 2 data from our collaboration with Moderna.

CHECKPOINTS AND AGONISTS

15:40 The CD47-SIRPα Myeloid Immune Checkpoint: Considerations for Targeting and Preclinical Characterization of BYON4228

Timo K. Van den Berg, PhD, Senior Director, Immuno-Oncology Research, Byondis

This presentation will discuss the biology of the CD47-SIRPα myeloid immune checkpoint and considerations for its therapeutic targeting in combination with, in particular, tumor-targeting antibodies. Furthermore, the preclinical development of BYON4228, a potentially best-in-class agent in the field, will be reported.

16:10 Design and Engineering of ATOR-4066 Using the RUBY Format: A Novel Neo-X-Prime bsab Targeting CD40 and CEA

Mattias Levin, PhD, Director, Antibody Technology Innovation, Alligator Bioscience AB

ATOR-4066 is a novel bispecific antibody, built in the RUBY format, targeting the tumor-associated antigen CEA (CEACAM5) on tumor cells and CD40 on myeloid cells. ATOR-4066 is designed to induce efficient CEA conditional activation of myeloid cells, as well as to drive uptake of neoantigen-containing tumor-derived material and subsequent cross-priming of tumor-specific T cells. This talk will describe the data-driven design of ATOR-4066.

16:40 Singularity Sapiens: A Next Generation Mouse Model for Developing Fully Human Single Domain Antibodies

LEVERAGEN

Weisheng Chen, PhD, Founder and CEO, Leveragen, Inc.

Single domain antibodies (sdAbs) are compact and versatile antigen binding modules with broad applications in immuno-, mRNA, and cell-based therapies. Conventional sdAb discovery methods such as camelid VHH humanization, human VH/VL libraries or transgenic models, have notable limitations that compromise efficacy. We have engineered a next generation mouse model that resolves these challenges, enabling the production of fully human sdAbs with significant diversity and biophysical properties.

17:10 Update on Numab's Affinity-Balanced PD-L1x4-1BBxHSA Trispecific Tumor-Targeted Immunotherapy

Stefan Warmuth, PhD, Vice President, Head CMC, Numab Therapeutics AG

We will provide an update on Numab's immunotherapy approach, which utilizes an affinity-balanced trispecific construct targeting PD-L1/4-1BB/HSA. Also other multi-specific programs for which affinity tuning is essential will be presented.

17:40 Adenovial Vector-Mediated Local IgA Production: A Novel Anti-Cancer Immunotherapy

Wouter P.R. Verdurmen, PhD, Assistant Professor, Medical Biosciences, Radboud University Nijmegen

We utilize a novel gene delivery approach using retargeted adenoviral vector as a novel anti-cancer immunotherapy. The adenoviral vector is targeted to specific cellular receptors overexpressed on tumor cells using binding proteins. We show that the local production of IgA antibodies and a checkpoint inhibitor leads to efficient tumor cell killing in a microfluidic all-human tumor-on-a-chip system by neutrophils through antibody-dependent cellular cytotoxicity, and by macrophages through antibody-dependent cellular phagocytosis.

18:10 Close of PEGS Europe Summit

14TH ANNUAL | LISBON, PORTUGAL

OPTIMISATION AND DEVELOPABILITY

Improving Candidate Selection and Lead Optimisation

TUESDAY 14 NOVEMBER

7:30 Registration Open and Morning Coffee

OPTIMISING DRUG PROPERTIES

8:25 Chairperson's Remarks
Andreas Evers, PhD, Principal Scientist, Computational Chemistry & Biology, Global Research & Development Discovery Technology, Merck Healthcare KGaA

8:30 KEYNOTE PRESENTATION: Thinking the Drug Lifecycle Through from End to Beginning: Developability Assessment and Optimization of Lead Candidates
Hitto Kaufmann, PhD, CSO, Hansa Biopharma
The exact sequence of a novel protein therapeutic needs to be locked-in early in development as subsequent investments are significant. However, many sequence attributes can cause obstacles during late-stage drug development. Experimental developability assessment of drug candidates requires mimicking stress conditions during manufacturing, drug application, or long-term storage and is time- and material-consuming. This is why developing predictive algorithms that allow drug candidate selection *in silico* is essential.

9:00 Non-mAb Biotherapeutics: A Paradigm Change for the Developability Assessment Concept?
Paul Wassmann, PhD, Senior Principal Scientist, NIBR Biologics Center, Novartis
Unmet needs in pharmaceutical area require development of complex, heavily engineered biotherapeutics, which are often based on non-mAb formats. Limited applicability of the mAb-centric developability assessment concept for these new formats will be highlighted. Importance of early identification of critical molecular parameters will be shown on examples such as assessment of parameters governing (short-term) stability during lead optimization phases and work-flows for synergistic in-silico/ in-vitro assessment of PTM liabilities.

9:30 Embedding Dynamics in Intrinsic Physicochemical Profiles of Market-Stage Antibody-Based Biotherapeutics
Giuseppe L. Licari, PhD, Lead Scientist, Computational Structural Biology, Global Drug Product Development - BDC, Merck Serono SA
This presentation explores the integration of dynamics into the intrinsic physicochemical properties of antibody-based therapeutics with the aim to better understand and predict protein behavior in different environments and formulations.

10:00 Comparing Potential Bispecific Formats of Trastuzumab and a Humanized OKT3
Catherine Bladen, PhD, COO, Absolute Biotech
Not every antibody can be combined to produce well-behaved multi-specifics. The valency and geometry of each design can determine the production, target engagement and ultimately the requisite biological functions. In this case study, we selected two established antibody therapeutics, trastuzumab and a humanized OKT3 to produce 20 different bispecific formats to compare the feasibility of each format.

10:15 Case Studies About Innovative Recombinant Protein Vaccines of the VRI/ Linkinvax Dendritic Cell-Targeting Platform
Thierry Menguy, PhD, Head, CMC Projects, LinkinVax
LinKinVax's ambition is to disrupt vaccine development using a unique, clinically safe, dendritic cell targeting vaccine platform inherited from VRI/INSERM allowing the development of recombinant protein vaccines against multiple pathogens and cancer.
cGMP manufacturing at LinKinVax relies some of downstream process and formulation adaptations specific to physicochemical properties of vaccines. We will present how we achieved large scale productions of candidates of the pipeline with GTP Bioways.

10:30 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

IMMUNOGENICITY RISK ASSESSMENT

11:15 Approaches to Immunogenicity Risk Assessment of mRNA-LNP Products
Sophie Tourdot, PhD, Immunogenicity Sciences Lead, BioMedicine Design, Pfizer Inc.
The LNP-mRNA platform is generating considerable interest in the field of immunotherapy. To date, there are no specific regulatory guidelines for the identification and mitigation of unwanted immunogenicity risk factors for LNP-mRNA products. Here, we present a strategy utilizing a suite of *in vitro* immunogenicity/reactogenicity assays that could be applied early in drug discovery to guide the design and optimization of LNP-mRNA therapeutics to reduce immunogenicity risk factors.

11:45 Graph-pMHC: Graph Neural Network Approach to MHC Class II Peptide Presentation and Antibody Immunogenicity
Will Thrift, PhD, Senior Artificial Intelligence Scientist, Genentech
Antigen presentation of MHC Class II plays an essential role in mediating the anti-drug response to large-molecule drugs. Such a response reduces drug efficacy and potentially causes safety concerns. Here, we develop graph-pMHC, a state-of-the-art graph neural network approach to predict pMHCII presentation. We further create an antibody drug immunogenicity dataset from clinical trial data, and develop a method for measuring anti-antibody immunogenicity risk using pMHCII presentation models.

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OPTIMISATION AND DEVELOPABILITY

Improving Candidate Selection and Lead Optimisation

12:15 Accelerating Antibody Discovery for Difficult Targets through mRNA Immunization and Beacon Single Cell Technology

Francois Romagne, PhD, Scientific Director, MI-mAbs

.Despite demonstrated efficiency in antibody generation, classical immunization strategies and subsequent hybridoma generation often face strong limitations when it comes to poorly immunogenic membrane proteins with short extracellular domains. Indeed, even if a few antibodies can be obtained with repeated campaigns, only limited diversity and molecular characteristics are achieved, resulting in difficulties in selecting good candidates for pharmaceutical developments. Innovative approaches combining RNA immunization and single cell screening provide unique opportunities to dramatically speed up antibody discovery against such challenging targets. In the presentation, obtention of large collections of antibodies with both molecular and function diversity against a difficult GPCR and ion channel will be described using these strategies.

12:45 Session Break

12:55 LUNCHEON PRESENTATION: Comprehensive Size Distribution Analysis of Adeno-Associated Virus Fill-States

Nikki Machalek, Scientist II, KBI Biopharma

Recombinant adeno-associated viruses (AAV) are used as a vector for gene therapy. AAV products are composed of a proteinaceous capsid that encapsulates the single stranded DNA genome. Preparations of purified AAVs typically contain capsid species ranging from empty capsids, partially-packaged capsids and over-packaged capsids that contain more than the full complement of intended DNA. Characterization and quantification of these species is necessary to ensure safety and efficacy of gene therapy treatments.

13:25 LUNCHEON PRESENTATION II: Empowering Therapeutic Antibody Development

Amanda Grimm, Senior Segment Marketing Manager, Antibody Drug Discovery, GenScript USA Inc.

Antibody-based therapeutics have transformed drug development, offering precise treatments for diseases. GenScript empowers antibody development from discovery to manufacturing, providing tools and services for every step. Our methods ensure high-quality, effective antibodies. We also offer reagents and instruments for purification, saving time and boosting efficiency. Join us to explore GenScript's solutions for therapeutic antibodies, enhancing your development efforts for innovative treatments.

13:55 Session Break

IN SILICO AND MACHINE LEARNING APPROACHES TO DEVELOPABILITY AND BIOLOGICS DRUG DESIGN

14:05 Chairperson's Remarks

Hitto Kaufmann, PhD, CSO, Hansa Biopharma

14:10 KEYNOTE PRESENTATION: Updated Therapeutic Antibody Profiling: The Developability Risk of Antibodies with Lambda Light Chains

Charlotte M. Deane, PhD, Professor, Structural Bioinformatics, Statistics, University of Oxford; Chief Scientist, Biologics AI, Exscientia

Here we update our Therapeutic Antibody Profiler (TAP) tool to use the latest data and machine learning-based structure prediction methods, and apply this new protocol to evaluate developability risk profiles for κ-antibodies and λ-antibodies based on their surface physicochemical properties. We also analyse the population of high-risk antibodies, highlighting opportunities for strategic library design or directed mutagenesis approaches that TAP suggests should enrich for more developable λ-based candidates.

14:40 Predicting Antibody Developability Using Machine Learning

Peter M. Tessier, PhD, Albert M. Mattocks Professor, Pharmaceutical Sciences & Chemical Engineering, University of Michigan

We report a high-throughput protein engineering method for rapidly identifying antibody candidates with both low self-association and high affinity. We conjugate IgGs that strongly self-associate to quantum dots and use these conjugates to enrich yeast-displayed antibody libraries for variants with low levels of immunoconjugate binding. Deep sequencing and machine learning analysis enables identification of extremely rare variants with co-optimized levels of low self-association and high affinity.

15:10 Next-Generation Biologics Engineering Platform: From Conventional Screening to Early Multiparameter Deep Characterization and Machine Learning-Based Properties Prediction

Ernst Weber, PhD, Head, Molecular Design & Engineering, Bayer AG

The presentation will focus on a new end-to-end high-throughput biologics engineering platform. It describes the generation and multiparameter characterization of large panels of biological molecules enabling short design and learning cycles. Here, we report on how we apply this new high-throughput engineering platform for parallel multiparametric optimization of protein therapeutics and how these high-quality datasets can be applied for machine learning applications.

15:40 Advanced computational tools and experimental methods to approach antibody developability

Thomas Cornell, Ph.D., Senior manager, Protein Engineering, Protein Engineering, Abzena

A crucial part of any drug development program is antibody developability both in identifying; and reducing the potential risk of a pre-clinical lead candidate. In this talk, we highlight computation tools that have been developed to aid antibody developability including iTope AI, a predictive tool to determine immunological risk of a protein sequence, as well as *in silico* assessment for identification and removal of sequence liabilities early in the developmental cycle.

15:55 *In Silico* and *in vitro* Toolbox for Developability Screening of Novel Modalities

Eddy Berthier, Associate Principle Scientist Pharmaceutical Development, Drug Product Services, Lonza

A comprehensive understanding of the physicochemical characteristics and liabilities of diverse novel modalities is often lacking, posing a risk to a successful and timely development. Our strategy can overcome these risks by rapidly evaluating several candidates with minute amounts of material,

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clearing the first step in the path to IND via a combination of in-silico and in-vitro approaches, e.g. viscosity prediction, high throughput subvisible particle assessment and automated data visualization workflows.

16:10 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Towards Biologics by Design: Computational & AI-Based Optimization of Multi-Specific Protein Therapeutics

Norbert Furtmann, PhD, Head, Computational & High-Throughput Protein Engineering, Large Molecule Research, Sanofi

Sanofi's automated high-throughput engineering platform enables the fast generation of large panels of multi-specific antibody variants giving rise to big data sets. By mining our data sets we were able to extract engineering patterns and to develop AI-based virtual screening workflows to guide the exploration of huge design spaces within biologics drug discovery.

17:30 Developability Strategy for Large Molecule Therapeutics: Integrating *in silico* and Wet Lab Approaches

Maniraj Bhagawati, PhD, Lab Head, Functional Characterization, Large Molecule Research, Roche pRED

Developability assessment of drugs during the discovery phase is critical to ensure the manufacturability, safety, and efficacy of selected candidates and thus improve the likelihood of clinical success. In this presentation, I will describe the developability framework at Large Molecule Research, pRED, Roche, with a special focus on assessment of molecule suitability for high concentration formulations and automation approaches for high-throughput developability analysis.

18:00 Optimisation of Antibody Developability Properties Using Deep-Learning Predictive Models

James R. Apgar, PhD, Associate Research Fellow, BioMedicine Design, Pfizer Inc.

For an antibody to be a successful therapeutic candidate many competing factors must be optimised simultaneously including desired binding affinities, good biophysical characteristics, and low immunogenicity. Here we will discuss the development of interpretable, biophysically-meaningful, deep-learning predictive models to optimised viscosity and other developability properties to accelerate the discovery and development process. These methods, along with high-throughput screening allow for rapid identification of lead molecules with good biophysical characteristics.

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Optimisation and Developability Conference

10TH ANNUAL | LISBON, PORTUGAL

ANALYTICAL CHARACTERISATION OF BIOTHERAPEUTICS

Developing Well-Characterized Novel Biologics

WEDNESDAY 15 NOVEMBER

7:30 Registration Open and Morning Coffee

CHARACTERISATION OF NOVEL BIOTHERAPEUTICS

8:25 Chairperson's Opening Remarks
Christian Graf, PhD, Fellow, Scientific Office, Novartis TRD Biologics

8:30 Challenges of Working with a Two-Faced Bispecific — One Size Does Not Fit All
Laura Sewell, Scientist, Biopharmaceutical Development, AstraZeneca
Showcasing a bioassay CMC strategy for a challenging bispecific and the steps taken to bring this molecule to the market. Two checkpoint inhibitor targets on a bispecific which require a suite of bioassays to measure potency. Exploring cell-based functional assays and multiple binding assays including dual-binding to understand benefits/drawbacks of each to build a comprehensive control strategy.

9:00 Antibody Fragment Drug-Conjugates (FDCs): Analysing Novel Formats with High DAR
Ioanna Stamati, PhD, Team Leader, Bioconjugation, Antikor Biopharma Ltd
FDCs, a new product class tailored for solid tumours, promise many advantages over ADCs, including rapid tumour penetration and faster clearance. However, due to the high DAR, new analytical strategies need to be applied as the linker-payload becomes a dominating feature by mass. We'll share LC-Mass spectrometric, Dynamic Light-Scattering, and Nanofluoresence-temperature unfolding data to show how we discover and characterize novel FDCs using our discovery engine.

9:30 Analysis of the Diverse Antigenic Landscape of the Malaria Invasion Protein RH5 by HT-SPR
carterra
Kirsty McHugh, PhD, Senior Postdoctoral Scientist, Fellow in Biochemistry, Pembroke College, University of Oxford
The *Plasmodium falciparum* RH5 protein is the leading blood-stage malaria vaccine target. However, the features of human vaccine-induced antibody responses that confer protection against red blood cell invasion are not well defined. Here, using HT-SPR we characterize over 200 human IgG monoclonal antibodies induced by the most advanced RH5 vaccine. This comprehensive dataset provides a framework to guide rational design of next-generation vaccines and prophylactic antibodies to protect against blood-stage malaria.

10:00 Session Break to Transition into Plenary Keynote

PLENARY KEYNOTE SESSION

10:10 Plenary Keynote Introduction
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

10:15 Benchmarking the Impact of AI Biologics Discovery and Optimisation for Pharma
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca
At PEGS Europe, we will present current *in silico* biologics design and optimisation technologies, with a focus on our internal efforts to benchmark the impact of combining novel *in silico* technologies with our existing biologics discovery platforms.

10:45 Keynote Chat
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

10:45 Plenary Fireside Chat
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

11:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:45 KEYNOTE PRESENTATION: Higher-Order Structure, Behavior, and Interactions of Novel Biotherapeutics
Mark McCoy, PhD, Principal Scientist, Quantitative Biosciences, MSD
We will present case studies of new modality behavior that includes Fc-Fusions, multi-specifics, biased cytokines, and ADCs. We show that a distant PTM can affect cytokine higher-order structure, leading to a mechanistic understanding of reduced activity; excipient interactions that affect multivalent VHH structure & dynamics, support patent filing, and self-interactions among Fc-fusion candidates lead to differentiated solution behavior that can contribute to developability assessments and support candidate selection.

12:15 Comprehensive Mutational Stability and Activity Profiles of Cancer Therapeutic Enzymes by Proximity-Based Sequencing
Michael Nash, PhD, Associate Professor, Chemistry & Biosystems Engineering, University of Basel/ETH Zurich
We report a novel ultrahigh-throughput screening method called enzyme proximity sequencing (EP-Seq) that accelerates enzyme engineering for cancer therapy. Our method leverages yeast display and deep mutational scanning to characterize the stability and catalytic activity of pooled enzyme variant libraries in a massively parallel fashion. Enzyme activity is read using radical-based proximity labeling and sequencing. This approach enables accelerated development of highly stable and active enzymes for metabolic cancer therapy.

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ANALYTICAL CHARACTERISATION OF BIOTHERAPEUTICS

Developing Well-Characterized Novel Biologics

12:45 Studying structure and function of antibodies using innovative chromatographic and mass spectrometric methodologies

Filip Borgions, Ph.D, Vice President, Global Head of Technical Operations, Argenx

Argenx is developing transformative antibodies, engineered at the variable and Fc region, for the treatment of a range of autoimmune diseases with high unmet medical need. In this presentation, the audience will be taken along an exciting analytical journey demonstrating the use of innovative chromatographic and mass spectrometric technologies to study structure and function of these unique therapeutic modalities.

13:15 Session Break

13:20 LUNCHEON PRESENTATION I: Manufacturing High Quality Proteins for Complex Applications

Juan Quintana, PhD, Technical Sales Manager, ACROBiosystems

Increasingly complex needs are arising in drug discovery, therapeutics and diagnostic fields. We provide unique set of solutions supporting these processes. Our best in class proteins are used across the world by biggest pharma companies. I describe how we strive for excellent quality manufacturing that can be easily transitioned to GMP. While showcasing some of our most important advancements in transmembrane protein Production and labeling techniques.

13:50 LUNCHEON PRESENTATION II: Robust Multi-Level LC-MS Workflows for Biosimilar Comparability Assessment

Nick Pittman, Marketing Manager, Global Biopharmaceutical Business, Waters Corporation

The biosimilars market is growing rapidly. More comprehensive analytical characterization gives greater confidence in the comparability, safety and efficacy of a biosimilar, allowing developers greater product understanding and the best chance of regulatory success Waters presentation highlights the enhancements of the Xevo G3 QTof mass spectrometer in a case study of biosimilar mAb characterization and comparability at intact, subunit, and peptide level, using app-based analysis within the compliance-ready waters_connect informatics platform

14:20 Session Break

14:30 Chairperson's Remarks

Dan Bach Kristensen, PhD, Principal Scientist, Symphogen

14:35 Multiple Biophysical Characterizations of Purified and in-Process AAV

Susumu Uchiyama, PhD, Professor, Biotechnology, Osaka University

Characterization methods of adeno-associated virus (AAV) have been developed.

15:05 Biophysical Evaluation of Efficient Hemin Scavengers in the Therapeutic Development for Hemolytic Disorders

Elena Karnaukhova, PhD, Research Chemist, Center for Biologics Evaluation and Research, US Food and Drug Administration

We consider therapeutic approaches to limit detrimental effects of extracellular hemin released from hemoglobin and discuss contemporary methods for the evaluation of hemin-protein interactions related to various tasks, from the manufacturing control of hemin impurities in blood-derived products to the development of efficient hemin scavengers. This talk provides an overview of the research studies towards therapeutic development for hemolytic disorders, with a focus on biophysical characterization of potential hemin scavengers.

15:35 Bruker's SPR Analyser 4 - State of the Art SPR Data Analysis

Sven Malik, Mr., Senior Application Specialist, Applications, Bruker Daltonics SPR

Possibilities of SPR data analysis collection using the Pro series instruments from Bruker. The SPR Analyzer 4 fulfills all customer needs for analyzing and processing data obtained from Bruker's Surface Plasmon Resonance instruments. It combines high performance and high flexibility within each step of data processing, from raw data to final reports. Each module was designed for intuitive use, containing a simplified layout to provide clear guidance for the user.

15:50 Using FO-SPR to select for efficient antigen binders in phage display

Kris Ver Donck, Vice President, Marketing & Applications, FOx BIOSYSTEMS

Phage display in conjunction with biopanning is a frequently used strategy in the selection process for expressed binding proteins with specificity to a target antigen. Here we present an FO-SPR based approach that combines both fast kinetic characterization and an efficient selection cycle. The assay is based on real-time kinetics monitoring, and binding can be assessed based on k_{on} and k_{off} behavior, which not available from classic endpoint characterization techniques.

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

ADVANCES IN ANALYTICAL TECHNIQUES & APPROACHES

17:00 MS-Based Cell Bioassays: A Novel Tool for Biotherapeutics Characterization

Christian Graf, PhD, Fellow, Scientific Office, Novartis TRD Biologics

Cell-based bioassays often face limitations with sample throughput, speed, and automation, and usually rely on indirect readouts utilizing reagents and labels. Here, we present an innovative feasibility study for development of a direct, fast, and label-free MS-based cell assay for therapeutic antibody potency characterization, using automated sample preparation, rapid MALDI-TOF mass spectrometry, and advanced data analytics. The MS cell bioassay provided comparable quantitative results to a routine luminescence-based method.

ANALYTICAL CHARACTERISATION OF BIOTHERAPEUTICS

Developing Well-Characterized Novel Biologics

17:30 Total Particle Analysis with Aura; Pathway to USP Validation and Product Release

Paul Dyer, PhD, Field Application Scientist, Halo Labs

The success of novel biotherapeutics, be it protein, gene or cell therapies has highlighted new challenges in the analysis of sub-visible particles (SVPs). Legacy technologies, light obscuration and flow imaging, and the guidelines that support their use, are outdated, lack sensitivity to detect low refractive particles, require large volumes, and cannot distinguish between SVP species. Aura® provides the tool to enable full and accurate analysis of SVPs in your therapeutic end-product.

18:00 Cryo-EM Structure and Epitope/Paratope Mapping of CEACAM5 Monoclonal Antibody Targeting

Alexey Rak, PhD, Head, Biostructure and Biophysics, Sanofi, France

CEACAMs are membrane-associated glycoproteins that are overexpressed in some tumor types. The antibody-drug conjugate, tusamitamab ravtansine, specifically recognizes the human CEACAM5. To understand the structural basis of this specificity, we mapped the epitope-paratope interface between hCEACAM5 and tusamitamab by various biophysical and biochemical methods and cryogenic electron microscopy. The Cryo-EM structure of the tusamitamabCEACAM5 complex revealed a discontinuous epitope involving residues in the two CEACAM5 domains and an N-linked mannose.

18:30 Interlaboratory Study of Multi-Attribute Method by Peptide Mapping Liquid Chromatography Mass Spectrometry (MAM) Performance across Novartis Analytical Development Sites

Maja Semanjski Curkovic, PhD, Science & Technology Expert, Process Analytical Sciences Tech R&D, Novartis Pharmaceuticals

MAM is an emerging mass spectrometry-based technique that allows for simultaneous monitoring of multiple quality attributes of therapeutic proteins on an individual amino acid level in a single analysis. We will present the implementation of an automated MAM platform from analytical characterization to process analytics on two robotic liquid handler types and the assessment of cross-site performance of the entire MAM workflow.

19:00 Close of Analytical Characterisation of Biotherapeutics Conference

10TH ANNUAL | LISBON, PORTUGAL

PROTEIN STABILITY & FORMULATION

Improving Efficacy and Mitigating Immunogenicity Risks

THURSDAY 16 NOVEMBER

7:30 Registration Open and Morning Coffee

AGGREGATION RISKS AND STABILITY PREDICTION

8:25 Chairperson's Remarks
Bernhard Valldorf, PhD, Targeting Director, Targeted mRNA Delivery, EMD Serono

8:30 Aggregation of Antibody during Inhalation Delivery: Risk, Countermeasure, and Potential Adverse Effects
Nathalie Heuze-Vourc'h, PhD, Research Professor, Research Center for Respiratory Diseases, Inserm, UMR
Inhalation is the gold standard for many drugs in respiratory medicine, to match the route to the target location. It consists of delivering a drug directly to the respiratory tract, as an aerosol. A major challenge associated with antibody aerosolization is instability, as they are exposed to a huge air-liquid interface along with shearing and rise in temperature, ultimately leading to aggregation, which may raise safety concerns.

9:00 Not the Usual Suspects: Alternative Surfactants for Biopharmaceuticals
Stefano Cucuzza, PhD, Postdoctoral Researcher, TRD Biologics & CGT, Novartis Pharma AG
Polysorbates are ubiquitously used as stabilizers in biotherapeutics drug product development. However, they are prone to degradation, increasing the risk of particles, chemical protein degradation, and potential adverse immune reactions. In this talk I will describe the development and characterization of novel alternative surfactants for biopharmaceuticals, created *ad hoc* to match the stabilization potential of polysorbates while being devoid of their drawbacks.

9:30 Tackle High-Concentration Biologics with the Right Toolkit
Andre Mueller, PhD, Marketing Manager, Biologics Solutions, Unchained Labs
High-concentration biologics for subcutaneous administration require complex formulation studies. Unchained Labs offers solutions to buffer exchange and quantify biologics, then screen quality, stability and viscosity. Join my talk for a case study using a high-throughput, low volume workflow to screen the effects of common excipients on four monoclonal antibodies at low and high concentrations. Impacts of formulation vary for each antibody and concentration, making access to effective screening tools crucial.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 KEYNOTE PRESENTATION: Science and Risk-Based Shelf-Life Prediction for Protein Biologics
Andrew A Kosky, PhD, Sr Director, Technical Development, Genentech Inc
This talk highlights the applications and challenges of predicting the long-term stability for protein biologics based on prior knowledge, enhanced product-scientific understanding, and Arrhenius model-based approaches.

11:15 Extrinsic Stabilization of Antiviral ACE2-Fc Fusion Proteins Targeting SARS-CoV-2
Hristo Svilenov, PhD, Associate Professor, Ghent University, Belgium
In this presentation, I will introduce a universal stabilization approach for ACE2-fusion proteins. The stabilization of the ACE2 domain is achieved by small molecular compounds that bind to the protein with high affinity and inhibit its enzymatic activity. The binding and stabilization mechanisms were studied with a combination of complementary techniques including differential scanning calorimetry, isothermal titration calorimetry, and hydrogen-deuterium exchange mass spectrometry.

11:45 Analytical Characterization Meets Molecular Modeling: *In silico* Forced Degradation Studies
Mitja Zidar, PhD, Senior Expert Science and Technology, Novartis
Forced degradation of biopharmaceutical proteins is a staple study of the industry and serves both to identify the proteins' weak points as well as to develop analytical methods to characterize them. But what if we could redesign force degradation studies with molecular modeling? The recent learnings on methionine and tryptophan oxidation, asparagine deamidation, and aspartate isomerization can be integrated directly from the literature into the development workflow.

12:15 Mass Photometry - A Fast and Accurate Mass Characterization of Biomolecules
Racha Majed, Technical Sales Specialist, Sales, Refeyn
Mass photometry is a single-particle analytical technology that measures the masses of biomolecules in their native states, in solution. The Two^{MP} mass photometer can measure masses of biomolecules between 30 kDa and 5 MDa and requires minimal sample for analysis. In this talk, we demonstrate the utility of the Two^{MP} in variety of contexts, including monitoring antibody-antigen interactions, quantifying small-molecule induced changes to complex formation, assessing sample purity and much more.

12:30 Spotlight on Light Scattering – How MALS and DLS Help with Measuring Product Parameters from Research to Production
Felix Gloge, PhD, Field Application Scientist, Waters | Wyatt Technology
Dynamic Light Scattering (DLS) is a powerful tool that can be used to quickly detect aggregates and perform formulation and stability studies. A more extensive characterization can be achieved by multi-angle light scattering instruments coupled to chromatography systems (SEC-MALS and FFF-MALS). We will also talk about real-time MALS and how it can be used for PAT-applications by enabling live access on attributes such as molar mass, size and particle concentration.

12:45 Session Break

12:50 LUNCHEON PRESENTATION I: Breaking Through the Challenges of rAAV Purity Characterization by Capillary Electrophoresis
Ana Carreras González, Ms, Analytical Development, Viralgen
Capillary Electrophoresis (CE-SDS) offers a state-of-the-art approach with high resolution and sensitivity for the characterization of rAAV purity under GMP standards.
This strategy provides a semi-quantitative estimate of drug product purity for quality control routine.
In this talk, we will discuss the challenges faced and the solutions achieved during CE-SDS implementation, all together with the GMP validation process of this analytical method.

10TH ANNUAL | LISBON, PORTUGAL

PROTEIN STABILITY & FORMULATION

Improving Efficacy and Mitigating Immunogenicity Risks

13:20 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

13:50 Dessert Break in the Exhibit Hall & Last Chance for Poster Viewing

ROUNDTABLE BREAKOUT DISCUSSIONS

14:45 Roundtable Breakout Discussions

Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

TABLE 3: Subcutaneous Administration and Immunogenicity Risk- Current Understanding and Future Considerations Including Novel Modalities

Karoline B. Bechtold-Peters, PhD, Senior Strategy & Technology Leader, Pharmaceuticals & Biopharma Process, Novartis Pharma AG

- Is SC administration more immunogenic than other routes?
- What are contributing attributes (aggregates, oxidized species, injection rate, protein concentration, formulation, impurities) and how can these attributes be assessed patient-centric?
- What are appropriate models (*in vitro, in vivo*) used to determine immunogenicity, and can these form the basis for specifications?
- How immunogenic are new modalities that deviate from standard monoclonal antibody platforms?

TABLE 4: mRNA Delivery & Formulation - Challenges and Outlook

Bernhard Valldorf, PhD, Targeting Director, Targeted mRNA Delivery, EMD Serono

- What are the current challenges and limitations in mRNA delivery, and how can they be overcome?
- What are the key considerations when designing delivery systems for targeted mRNA delivery? How can we optimize the delivery efficiency and specificity?
- What are some of the most promising applications of targeted mRNA delivery in medicine (e.g. *in vivo* CAR-T production)? What are the benefits compared to other strategies?

15:25 Session Break

FORMULATION DEVELOPMENT AND CHALLENGES FOR IV AND SUBCUTANEOUS ADMINISTRATION

15:35 Chairperson's Remarks

Karoline B. Bechtold-Peters, PhD, Senior Strategy & Technology Leader, Pharmaceuticals & Biopharma Process, Novartis Pharma AG

15:40 Case Studies on the Application of New Tools and Approaches for Current Challenges in Formulation Development of Antibody-Based Drugs

Michael Siedler, PhD, Section Head, NBE Formulation Sciences & Process Development, Abbvie Deutschland GmbH & Co. KG

The presentation will provide an overview and case studies on generating data for developing high & ultra-high concentrated protein formulations by using new high-throughput formulations screening methods. We will also discuss challenges around (re)-using of analytical data for A.I. applications.

16:10 Interactions between Preservatives and an IgG1 mAb in Support of Multi-Dose Formulation Development for Biologics

Ramesh Kumar Shanmugam, PhD, MBA, Associate Director, Biopharmaceutical Development, AstraZeneca

Multi-dose formulations contain preservatives to prevent growth of microorganisms during the in-use timeframe. Destabilization of proteins by preservatives is a major challenge in the development of multi-dose biologics. Evaluated HDXMS to measure changes in structure and flexibility of antibody in the presence of preservatives. Results identified a common hot spot for preservative interaction and showed a pattern of altered antibody backbone flexibility in the presence of preservatives.

16:40 Understanding and Overcoming Surfactant-Related Stability Challenges

Lisa Dietel, PhD, Scientist, Pharmaceutical and Processing Department, Novel Formats, F. Hoffmann-La Roche AG

This talk delves into the surfactant-related stability challenges encountered in the biopharmaceutical industry. In particular, it will cover contributing CMC factors leading to free fatty acid particles derived from polysorbate formulations, and protein-silicone oil (PDMS) particles observed in poloxamer 188 (P188) formulations. This talk will also discuss the general risk profiles and mitigation approaches associated with different routes of administration (e.g., IV, SC, IVT).

17:10 Development of a New High-Concentrated Formulation of Anti-Tumour mAbs for Subcutaneous Administration: Anti-EGFR mAb Study Case

Kathya Rashida de la Luz Hernandez, PhD, Head, Analytical, Center of Molecular Immunology

Due to the high doses required in most treatments using mAbs and the small volume that is admitted for s.c., we must obtain mAbs formulations at high concentrations. A staged screening methodology was performed to determine the best formulations for nimotuzumab. This mAb is an anti-EGFR antibody, used in the treatment of some tumours. The nimotuzumab was formulated with >150 mg/mL and its characterization, stability, and anti-tumour effect were determined.

17:40 Improving Safety and Dose Accuracy of IV Administration for Protein Drug Products

Qingyan Hu, PhD, Associate Director, Protein Formulation Development, Regeneron Pharmaceuticals, Inc.

IV admixture compatibility and in-use stability are critical components in ensuring patient safety and product efficacy. Case studies on antibody drug products will be presented, including preventing low dose adsorption and using proper ancillaries for dose preparation to ensure dose accuracy, as well as defining in-use time and minimizing IRRs to improve safety. The use of CSTD for dose preparation and administration will also be discussed.

18:10 Close of PEGS Europe Summit

6TH ANNUAL | LISBON, PORTUGAL

CELL LINE AND SYSTEMS ENGINEERING

Advancing the Protein Expression and Production Toolbox

TUESDAY 14 NOVEMBER

7:30 Registration Open and Morning Coffee

APPLYING DATA SCIENCE TO ENHANCE PROTEIN EXPRESSION

8:25 Chairperson's Opening Remarks
Nicola Burgess-Brown, PhD, Director of Enzymology and Protein Engineering, Exact Sciences Innovation

8:30 FEATURED PRESENTATION: Accuracy and Data Efficiency in Deep Learning Models of Protein Expression
Diego A. Oyarzun, PhD, Reader in Computational Biology, Informatics Forum, University of Edinburgh
Deep learning has emerged as a promising approach to build sequence-to-expression models for strain optimization. But these need large and costly data that create steep entry barriers for many laboratories. We will discuss the relation between accuracy and data efficiency in a large atlas of machine learning models. Our results provide guidelines for balancing cost and quality of training data, and help promote adoption of deep learning in strain engineering.

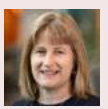
9:00 Codon Language Models for Protein Engineering
Carlos Outeiral, PhD, Eric and Wendy Schmidt AI in Science Research Fellow, Department of Statistics, University of Oxford
Many state-of-the-art tools in protein bioinformatics make use of latent representations from protein language models trained on hundreds of millions of amino acids sequences. In this work, we suggest that training a large language model on cDNA sequences (codons) instead of protein sequences (amino acids) leads to effective, parameter-efficient representations that can be used for a variety of tasks, including prediction of protein and transcript abundance.

9:30 Automated Model Based Optimisation of Difficult-to-Express Protein Processes in a Robotic Facility
Peter Herr Neubauer, PhD, Lab Head, Bioprocess Engineering, TU Berlin
The KIWI-biolab enables efficient recombinant bioprocess development and optimization on a robotic platform with fully automatic orchestration of parallel bioreactor systems of different scales, analytical instruments and a mobile laboratory robot. Based on FAIR data principles it allows self-controlled parallel fed-batch cultivations, integrated sample analysis and mathematical model-based parameter calibration and CQA optimisation. The power of the platform is demonstrated by industrially relevant recombinant processes including Fabs, elastins and hydrogenase.

10:00 Improving Production of Biologics Using Data Science
Claes Gustafsson, Ph.D, CCO & Co-Founder, ATUM
Therapeutic biologics, including antibodies, enzymes, mRNA and more are manufactured from biological systems. The COVID pandemic provided strong incentive to the industry to speed up the manufacturing process and bring drugs to the market faster. This presentation will illustrate how transposons, machine learning and a systematically varied data is utilized to design and optimize biological sequences that has enabled >20 IND filings

10:30 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Using Machine Learning to Predict Protein Expression
Lovisa Holmberg Schiavone, PhD, Director, Discovery Biology, Discovery Sciences, R&D, AstraZeneca
We have developed a machine learning model to predict protein expression. Plans will be shared for model improvement by (1) streamlining data registration, (2) using yield values, (3) incorporating protein sequence embeddings based on AI language models, and (4) leveraging external datasets. Limited availability of training data is a key blocker. We are exploring sharing data via a pre-competitive consortium in collaboration with EMBL-EBI and other academic and industry partners.



11:45 KEYNOTE PRESENTATION: Approaches to High-Throughput Expression and Machine Learning at GSK
Kate J. Smith, PhD, Director, UK Protein & Cell Sciences, GSK
Rapid generation of quality reagents is essential for successful drug discovery. Minimizing reagent design-make-test cycles decreases cost and increases success. We have developed high-throughput mammalian and *E. coli* expression systems to screen for optimal expression. We are using machine learning and protein design approaches to inform construct design and increase the success of our reagents for several applications. This presentation introduces our high-throughput expression systems and our approaches to design.

12:15 Quantitative Synthetic Biology to Advance Biologics Production
Mark Stockdale, Strategic Alliance Director, Asimov
Here we present the Asimov CHO Edge platform, which builds on the current state of the art for CLD by integrating expanded genetic tools with data driven models. Incorporating a GS knock-out CHO host, a hyperactive transposase, a library of >2000 characterized genetic elements, and advanced computational tools, the CHO Edge platform empowers researchers to explore the vector design space and achieve greater expression efficiency and quality.

12:45 Session Break

12:55 LUNCHEON PRESENTATION I: Efficient Therapeutic Development Using The Pfenex Expression Technology® Platform
Jeff Allen, SVP Process and Analytical Development, Analytical, Primrose Bio
The Pfenex Expression Technology® is a commercially validated P. fluorescens based platform used for recombinant protein production. Case studies are discussed demonstrating how the Pfenex toolbox of genetic elements and host strains enabled rapid exploration of expression strategies for challenging protein scaffolds, including proteins engineered for site-specific chemical modification to enable the development of products such as antibody drug conjugates for use as human therapeutics.

CELL LINE AND SYSTEMS ENGINEERING

Advancing the Protein Expression and Production Toolbox

13:25 LUNCHEON PRESENTATION II: Leveraging the BioXp Platform for Automated Plasmid Construction at Acies Bio

TelesisBio

Aleksander J. Kruis, Head of Metabolic Engineering, R&D, Acies Bio

Strain design and optimization requires testing and expressing large numbers of genes, however assembling large numbers of these constructs is a laborious and time-consuming bottleneck. Join Acies Bio, to learn how they have successfully addressed this challenge by leveraging Telesis Bio's BioXp® automated synthetic biology workstation to enable rapid overnight synthesis of enzyme homologs, synthesis of expression cassettes, and parallel construction of CRISPR target plasmids.

13:55 Session Break

ENGINEERING AND DEVELOPING HOST CELL LINES

14:05 Chairperson's Remarks

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

14:10 Directed Evolution of Bovine Enterokinase from Inclusion Body to Soluble Protein Expression

Paul Dalby, PhD, Professor, Department of Biochemical Engineering; Co-Director, Future Targeted Healthcare Manufacturing Hub, University College London

Bovine enterokinase light chain is used for affinity-tag removal. Expression in *E. coli* leads to insoluble inclusion bodies. Directed evolution yielded 321 unique variants, with up to >11,000-fold increased soluble expression, mainly due to stability. Codon optimisation improved expression at 37°C. However, non-optimised codons and expression at 30°C gave the highest activities. Partial least squares analysis revealed that soluble variants tended to combine stabilising mutations outside the active site.

14:40 A Next-Generation pET System for Bacterial Protein Production

Morten Nørholm, PhD, Research Group Leader, Novo Nordisk Foundation Center for Biosustainability, Technical University of Denmark

The pET plasmids constitute the most popular protein production system. Using synthetic experimental evolution, we have improved the performance of several of the pET genetic modules and bacterial strains. In addition, we have developed an extremely simple method for making recombinant DNA. The approach and the genetic modules will be combined into a next-generation pET system.

15:10 Novel Strategies for Protein Production Using *Pichia pastoris*

Claudia Rinnofner, PhD, Founder & CEO, myBIOS GmbH

Recombinant protein production allows us to create smart materials and catalysts. Our mission is to find solutions to produce biomaterials using the yeast *Pichia pastoris*, which is an efficient alternative for recombinant production, combining the simplicity of bacterial expression with some essential features of higher eukaryotic hosts. We build on over 15 years of experience in toolbox development and expression to overcome hurdles and constantly apply new strategies.

15:40 The Future of Microbiology: Sustainable Alternatives for Food & Beverage

MOLECULAR DEVICES

Carola Mancini, European Field Applications Scientist, BioPharma, Molecular Devices

The landscape of the food and beverage industry is undergoing a transformative shift, driven by the dual imperatives of sustainability and innovation. This presentation paints the picture of a customer's innovative leap, harnessing the power of microalgae metabolism. Our showcase will also spotlight the QPix Microbial Colony Picker, an instrumental player in forging ahead with sustainable alternatives for industries far and wide.

15:55 Picodroplets for Cell Line Engineering: a Novel Automation Approach

Sphere Fluidics

Richard Hammond, MA MEng., CTO, Sphere Fluidics Limited

The development process for cell lines is complex and laborious, with increasing expectations for supporting in-process data. We will show how microfluidic-enabled picodroplets deliver integrated, user-friendly, automated workflows where millions of individual cells are assessed daily, and the best single cells selected - in an environment that maintains high cell viability and outgrowth. We will introduce Cyto-Mine®, a platform that enables a step-change in speed and scale of working.

16:10 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Genome-Wide Virus-Free CRISPR Screening Platform for Identifying Novel Engineering Targets in Mammalian Cells

Jae Seong Lee, PhD, Associate Professor, Applied Chemistry & Biological Engineering, Ajou University

Mammalian cells are the preferred host cells for therapeutic protein production and have been engineered to contain desired attributes for increased protein production. To identify novel engineering targets, laborious and time-consuming empirical approaches have been attempted. Here, I present a genome-wide CRISPR-Cas9 screening platform for CHO and HEK293 cells using a virus-free, recombinase-mediated, cassette exchange-based gRNA integration method to identify novel targets for high productivity and culture-stress resistance.

17:30 The Potential of Emerging Sub-Omics Technologies for CHO Cell Engineering

Christoph Keysberg, PhD, Research Assistant, Biberach University

In recombinant protein production with CHO cells, bottlenecks in productivity or product purity issues require a particular cellular or clonal mechanism to be analyzed. Emerging analytical techniques allow ever more detailed insights into cellular processes involved in protein expression or cultivation performance. Thus, we performed targeted studies on CHO sub-OMICs, including the miRNome, cell surfaceome, as well as secreted HCPs and extracellular vesicles, to address specific issues of biopharmaceutical production.

18:00 Getting the Most Out of Your Cells: Refining the Process for Higher Protein Yields

Jose Luis Corchero-Nieto, PhD, Senior Scientist, Nanobiotechnology Group, CIBER-BBN & University Autonoma de Barcelona

In the last years, we have been expressing different recombinant proteins in human cells, by PEI-based transfection and transient gene expression. With the aim of improving expression levels, we explored different parameters and conditions, implementing in our process those changes that improved protein yield. In our talk, we will detail such continuous process, and show where we started, and where we are now.

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Cell Line and Systems Engineering Conference

16TH ANNUAL | LISBON, PORTUGAL

OPTIMISING EXPRESSION PLATFORMS

Employing Cell Factories for the Enhanced Production of Recombinant Proteins

WEDNESDAY 15 NOVEMBER

7:30 Registration Open and Morning Coffee

OVERCOMING EXPRESSION AND PRODUCTION CHALLENGES OF DIFFICULT-TO-EXPRESS PROTEINS

8:25 Chairperson's Opening Remarks
Ana Sofia Coroadinha, PhD, Lab Head, Health & Pharma Division, Animal Cell Technology Unit Cell Line Development and Molecular Biotechnology Lab, IBET

8:30 Development of Specialized Bacterial Strains for High-Level Production of Recombinant Membrane Proteins
Georgios Skretas, PhD, Director, Institute for Bio-innovation, Biomedical Sciences Research Center "Alexander Fleming;" Founder & CEO, ResQ Biotech

We will describe the development of *E. coli* SuptoxD and SuptoxR, two specialized strains for high-level recombinant membrane protein (MP) production. These engineered strains can: (1) suppress the toxicity that frequently accompanies MP overexpression, thus enabling enhanced levels of final bacterial biomass; and (2) markedly increase the cellular accumulation of membrane-embedded protein. Combined, these two positive effects result in dramatically enhanced volumetric yields for various prokaryotic and eukaryotic recombinant MPs.

8:50 Membrane Protein Production Using Insect Cells
Alice Rothnie, DPhil, Senior Lecturer, Biochemistry, Aston University

Membrane proteins play important roles in cell signaling, the influx and efflux of nutrients and metabolites, and many are potential drug targets. For their structural and functional analysis, high yields of correctly folded and modified protein are needed. Multidrug resistance protein 4 (MRP4/ABCC4) is a multi-substrate primary transporter that has been expressed using both recombinant baculovirus infection of Sf9 insect cells, and baculovirus-mediated transduction of Freestyle HEK cells.

9:10 *Lactococcus lactis*, a Promising Cell Factory to Functionally Express Membrane Proteins
Annie Frelet-Barrand, PhD, Researcher, MN2S, Institut FEMTO-ST

Membrane proteins (MPs), important drug targets, display crucial functions in organisms but their study remains difficult (hydrophobicity and low abundance). Their overexpression is mandatory for structural and functional characterizations but this strategy could encounter obstacles. Using NICE system and *L. lactis* strains, almost 100 MPs were expressed of which one eukaryotic MP at high yield allowing formation of intracellular vesicles. Finally, *L. lactis* represents an interesting system for MP expression.

9:30 Fyonibio's Versatile Cell Line Expression Platforms for the Development of Complex Molecules
Lena Tholen, Director, Cell line and Bioprocess Development, FyoniBio GmbH

Here FyoniBio presents its versatile highly productive expression platforms, the mammalian host cell systems CHOnamite®, for e.g. bi-specific mAbs incl. our CHOFlow® for afucosylated antibodies and the human GEX® platform for the development and production of complex glyco-biopharmaceuticals in the desired quality. A case study from a customer project demonstrates the suitability of our cell line platform for the production of complex bispecific mAbs in combination with bioprocess optimization capabilities.

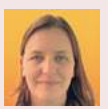
9:45 From Modular DNA Assembly to Recombinant Protein Production at Polyplus
Marine Houdou, Genetic Engineering Specialist, Polyplus

With recent acquisitions of e-Zyvec and Xpress Biologics, Polyplus offers now a unique integrated pDNA service with plasmid engineering and manufacturing. Our unique DNA assembly technology and proprietary software allow the tailor-made design and production of any plasmid. Synergistically, the 30+ years of combined expertise at Xpress Biologics reinforces our services at Polyplus to support recombinant protein manufacturing from 100 mg to 50 g at Research, GLP and GMP grade.

10:00 Session Break to Transition into Plenary Keynote

PLENARY KEYNOTE SESSION

10:10 Plenary Keynote Introduction
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET



10:15 Benchmarking the Impact of AI Biologics Discovery and Optimisation for Pharma
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

At PEGS Europe, we will present current *in silico* biologics design and optimisation technologies, with a focus on our internal efforts to benchmark the impact of combining novel *in silico* technologies with our existing biologics discovery platforms.

10:45 Keynote Chat
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

10:45 Plenary Fireside Chat
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

11:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:45 FEATURED PRESENTATION: Cell Line Development and Engineering Strategies for the Manufacture of Lentiviral Gene Therapy Viral Vectors
Ana Sofia Coroadinha, PhD, Lab Head, Health & Pharma Division, Animal Cell Technology Unit Cell Line Development and Molecular Biotechnology Lab, IBET

The gene and cell therapies market is growing, with several products being approved every year. The expression of viral vectors for gene therapy is challenging however, since these often require the expression of toxic proteins posing obstacles in cell line development. This work discusses the main challenges lentiviral vector cell therapies face, and presents strategies and novel technologies to be adopted to enable their effective manufacture.

16TH ANNUAL | LISBON, PORTUGAL

OPTIMISING EXPRESSION PLATFORMS

Employing Cell Factories for the Enhanced Production of Recombinant Proteins

12:15 Baculovirus-Free Expression of Virus-Like-Particles in Insect Cells for Antibody Development
Maren Schubert, PhD, Research Group Leader, Department of Biotechnology, Technical University of Braunschweig
The baculovirus expression vector system leads to high yields of Virus-like-Particles (VLPs). Yet, it´s time-intensive, inflexible in regard of protein ratios, its quality can be hampered by low cell viability, and last but not least, purification is challenging due to simultaneously produced baculoviral particles. The here-presented alternative of baculovirus-free VLP production in insect cells avoids the pitfalls of BEVS and produces VLPs in high quality and quantity for antibody development.

12:45 Harnessing Simplicity with the TheraPRO® CHO Media System Lonza
Josi Buerger, Associate Principal Scientist, R&D, Lonza Biologics
From generating high-producing clones to bulk drug substance with high protein titre and product quality.
The TheraPRO® CHO Media System builds on Lonza's longstanding expertise in protein production and adds in one critical element: simplicity. In this talk we will introduce the TheraPRO® CHO platform and discuss the scientific challenges of developing a media system that maintains excellent product quality from clone construction through to industrial scale up.

13:15 Session Break

13:20 LUNCHEON PRESENTATION: Best in Class Antiviral Antibodies from Cognate Recombinant Antibody Repertoires of Human Donors GenScript
Matthias Hillenbrand, PhD, Head, Infectious Disease Research & Biosafety Officer, Memo Therapeutics AG
Memo Therapeutics AG developed Dropzylla®, an antibody discovery platform based on a high-throughput conversion of B cell repertoires into immortalized mammalian-display biobanks. Deploying the platform, we identified potent nAbs from convalescent donors against BK virus and SARS-CoV-2, AntiBKV being in a pivotal phase II/III clinical trial with FDA fast-track designation. Currently, we work on the identification of a set of nAbs against HCMV, a severe threat to immunosuppressed individuals.

13:50 LUNCHEON PRESENTATION II: Strategies for Unveiling Optimal Bispecific Antibody Pairings WuXi Biologics
Julia Su, PhD, Associate Director of BD, Protein Sciences, WuXi Biologics
Bispecific antibody production presents challenges like heterogeneity, production complexity, and stability issues, which can impact the quality of the final product. This presentation will disclose the innovative strategies to address these challenges in drug development. It includes the initial small-scale high-throughput production of a vast number of bispecific antibodies in identifying optimal pairings, as well as later stage large-scale production. Real-world case studies will showcase the successful application of these strategies.

14:20 Session Break

OVERCOMING EXPRESSION AND PRODUCTION CHALLENGES FOR UNIQUE PROTEINS

14:30 Chairperson's Remarks
Mercedes Márquez Martínez, PhD, Technical Coordinator & Acting Scientific Director, Protein Production Platform (PPP) – Nanbiosis, Autonomous, University of Barcelona (UAB)

14:35 KEYNOTE PRESENTATION: An Automated DNA Assembly Framework Enables Rapid and Scalable Plasmid Generation for Drug Discovery Applications
Robert G. Roth, PhD, Director, Protein Expression & Molecular Biology, Discovery Biology, R&D Biopharmaceuticals, AstraZeneca
Rapid and flexible construct generation at-scale is one of the most limiting first steps in the majority of drug discovery projects. The speed, quality, and cost of this process can be dramatically reduced by modular DNA design principles and automated fragmentation. We have designed a robust, multi-module golden gate-based cloning platform for construct generation with a wide range of applications.

15:05 Host Comparative Production of Recombinant Proteins for Assembling as Nano- and Micro-Scale Materials for Drug Delivery
Mercedes Márquez Martínez, PhD, Technical Coordinator & Acting Scientific Director, Protein Production Platform (PPP) – Nanbiosis, Autonomous, University of Barcelona (UAB)
Recombinant proteins can be artificially self-assembled in the form of functional structures with promising applications in the field of drug delivery via nanostructured protein-only drugs. The antigenic RBD domain of the SARS-CoV-2 spike was produced in several expression systems as a model to investigate the influence of the protein source in the production of nanoparticles and secretory microparticles. Both structures were generated in all cases but with different biophysical properties.

15:35 CLD Platform Optimization for Generation of High Titer CHO Cell Lines at Bioneer bioneer
Alexandra Baer, PhD, R&D Manager for Upstream Development of Mammalian Cells, Recombinant Proteins, Bioneer A/S
To strengthen our recombinant protein production capabilities Bioneer has established a cell line development platform in CHO DG44 cells. We have developed new expression vectors that show superior performance compared to commercial vector systems. Different product types like monoclonal antibodies, bispecific antibodies and enzymes have been expressed. Media and feed optimization boosted expression twofold resulting in yields of up to 6 g/L.

15:50 Solving a Key Challenge in Immunotherapeutic Production with the GS System® Lonza
Peter O'Callaghan, PhD, Head of Expression System Sciences (Biologics and Licensing), Lonza
Scientists and regulators across the globe have trusted the GS Gene Expression System® to expedite molecules to the clinic for over thirty years. With continuous market-driven innovation, the GS System® continues to keep pace with the evolving demands of biologics expression and production. In this talk, we present how Lonza's state-of-the-art capabilities in CHO cell line engineering have paved the way for a new host cell line that achieves specific product quality attributes relevant to major therapy spaces, especially the oncology and autoimmune areas.

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

16TH ANNUAL | LISBON, PORTUGAL

OPTIMISING EXPRESSION PLATFORMS

Employing Cell Factories for the Enhanced Production of Recombinant Proteins

17:00 Venom on Demand: Optimizing Snake Toxin Yield, Folding, and Purity in *E. coli* and *P. pastoris* with Biotinylation, Solubility, and Purification Tags

Esperanza Rivera de Torre, PhD, Assistant Professor, Center for Antibody Technologies, Department of Bioengineering, Technical University of Denmark

Animal venoms contain a plethora of biologically active toxins that have the potential to revolutionize antivenom development. However, producing functional toxins with the correct disulfide pattern is challenging. Our approach involves engineering co-chaperon systems in *Escherichia coli* and leveraging *Pichia pastoris*' secretory capacity to produce natural and designed toxins. Our optimized strategies allow for efficient toxin folding and purification, enabling downstream biotechnological applications.

17:30 Development of a Broadly Neutralizing Intranasal Anti-SARS-CoV2 Trimeric Sherpabody

Anna R. Makela, PhD, Senior Scientist, Department of Virology, University of Helsinki

SARS-CoV-2 blocking agents that are invulnerable to mutational viral variation and economical to produce are needed. TriSb92 is a highly manufacturable and stable trimeric antibody-mimetic sherpabody targeted against a conserved region of the viral spike glycoprotein. TriSb92 potently neutralizes SARS-CoV-2 and its variants. In mice, intranasal administration of TriSb92 before and after SARS-CoV-2 challenge can protect from infection, highlighting the potential of TriSb92 as a nasal spray for human use.

18:00 Recombinant Protein L: Production, Purification and Characterization of a Universal Binding Ligand

Stefan Kittler, PhD, Postdoc Researcher, Institute of Chemical Environmental & Biological, TU Wien

Protein L (PpL) is a universal binding ligand that can be used for the detection and purification of antibodies and antibody fragments. However, due to its current higher market price, PpL is still scarce in applications. We investigated the recombinant production and purification of PpL and characterized the product in detail. In my talk I present a comprehensive roadmap for the production of the versatile protein PpL in *E. coli*.

18:30 PANEL DISCUSSION: Protein Production Lab Challenges: Methodologies, Strategies, and the Art of Expressing Recombinant Proteins

Moderator: Richard Altman, MS, Field Application Scientist, Life Science Solutions, Thermo Fisher Scientific

Protein expression laboratories provide crucial support to drug discovery efforts. This panel discussion will focus on the concepts, technologies, and strategies necessary to meet the ever-increasing need for recombinant proteins.

- Know your protein!
- Strategies on how to manage multiple "top priority" projects
- Total workflow efficiency
- The importance of tech development to long term success
- Troubleshooting strategies or how much time should be spent before moving to the next option?

Panelists:

Nicola Burgess-Brown, PhD, Director of Enzymology and Protein Engineering, Exact Sciences Innovation
Peter Schmidt, Director Protein Biochemistry, CSL Research, Melbourne, Australia
Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

19:00 Close of Optimising Expression Platforms Conference

8TH ANNUAL | LISBON, PORTUGAL

PROTEIN PROCESS DEVELOPMENT

Optimizing Workflows to Streamline Bioproduction from Benchtop to Manufacturing

THURSDAY 16 NOVEMBER

7:30 Registration Open and Morning Coffee

QUALITY CONTROL

8:25 Chairperson's Remarks
Nicola Burgess-Brown, PhD, Director of Enzymology and Protein Engineering, Exact Sciences Innovation

8:30 Protein Quality after the Release from Microparticles
Julieta Maria Sanchez, Instituto de Biotecnologia y Biomedicina, Universidad Autonoma de Barcelona (UAB)
Inclusion bodies (IBs) are protein microparticles produced by bacterial overexpression of recombinant proteins. Because of the protein functionality and secretion properties, IBs have been used in biotechnology and biomedicine. We have developed artificial IBs that preserve the features of natural versions but also have a controlled composition, ensuring biocompatibility. Our focus lies in pointing out the performance and functional improvement of the protein released from both IBs and artificial IBs.

9:00 Targeting Every Human Protein: Challenges and Prospects
Opher Gileadi, PhD, Head, Protein Science SGC, Karolinska Institute
Structural genomics has encouraged the development of systematic approaches for expression and purification of previously unstudied proteins. Such approaches are increasingly pertinent, as unbiased "omic" studies discover new possible targets which have not been investigated at the protein level. Target2035 aims to generate chemical tools to all potential drug targets in the human genome. This will require innovative technologies as well as an international coordinated effort.

9:30 Developing a Robust Affinity Tag Platform Using Engineered Streptavidin
Fabian Mohr, PhD, Vice President Research & Development, IBA Lifesciences
Affinity chromatography protein purification is highly specific. For best results, affinity resins have to be stable across pH and temperature ranges, tolerate harsh clean-in-place procedures and various buffers. Strep-tag® technology - a highly specific affinity tag system based on streptavidin:biotin interaction, fulfills these conditions and only needs mild elution conditions. Besides excellent purification, a picomolar binding strength of the 3rd generation allows specific protein immobilization.

9:45 Platform integration for high-throughput functional screening applications
Zana Kapustina, PhD, Director of Product Management, Product Management, Atrandi Biosciences
Screening throughput is a common bottleneck in many research areas, including drug discovery and directed evolution. Microfluidic droplet sorting is the basis of high-throughput functional screens, yet its applicability is limited due to the technical complexity of integrating droplet analysis and manipulation. As a solution, Atrandi Biosciences' Styx platform enables custom droplet sorting workflows, which are necessary for the development of early-stage biological therapeutics or industrially important biocatalysts.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

PROTEIN PURIFICATION

10:45 Rapid Purification of Multi-Specific Antibodies Enabled by Introduction of Engineered Mutations
David J. Reczek, PhD, Head of US Biologics Research, Large Molecules Platform, Sanofi
We have designed and engineered a set of purification-enabling mutations into specific regions of multi-specific antibody chains that enables a highly effective, rapid and high-throughput, all affinity-based purification scheme for many different formats. This innovation can help accelerate the early identification of lead candidate molecules in research by allowing simple and fast isolation of highly pure material from mixtures of product-related impurities.

11:15 Enhancing Success Rates and Throughput of Protein Purification for Drug Discovery: A Medium-Scale Approach
Sandeep K. Talapatra, PhD, Leader Protein Science, Protein Cell & Structural Sciences, GSK
Recombinant protein production is crucial in contemporary drug discovery, contributing to target identification, screening, selectivity, and structural biology studies. Swift and top-quality protein production is crucial for successful drug development, where efficient recombinant protein production becomes necessary. Our team is continuously improving technology, utilising a medium-scale recombinant protein purification platform to enhance sophistication, throughput, optimisation, and finally, reducing time and costs at the early stages of drug discovery.

11:45 KEYNOTE PRESENTATION: Protein Purification Strategies Must Consider Downstream Applications and Individual Biological Characteristics
Kim Remans, PhD, Head, Protein Expression & Purification Core Facility, EMBL Heidelberg
Proteins are used as reagents in a broad range of scientific disciplines. The reliability and reproducibility of the obtained experimental data will largely depend on the quality of the (recombinant) proteins. Therefore, proper quality control throughout the entire protein expression and purification workflow is imperative. However, the specific features that need to be checked depend very much on both the biological characteristics of the protein and the intended downstream applications.

12:15 Reducing the Complexity of Protein Manufacturing: Streamlining the Workflow
Anis Larbi, PhD, Senior Manager Medical & Scientific Affairs, Beckman Coulter Life Sciences
Optimizing the outcome of protein production is possible when a holistic approach is implemented. Indeed, the quality of the end-product will be improved and more reproducible when the overall workflow in place is optimized and monitored. We will discuss how technological platforms integrated to a workflow improve reproducibility and robustness of the process. The various steps of protein manufacturing will be covered from inception of the idea to the final quality control of the end-product.

12:45 Session Break

12:50 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

PROTEIN PROCESS DEVELOPMENT

Optimizing Workflows to Streamline Bioproduction from Benchtop to Manufacturing

13:50 Dessert Break in the Exhibit Hall & Last Chance for Poster Viewing

ROUNDTABLE BREAKOUT DISCUSSIONS

14:45 Roundtable Breakout Discussions

Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

TABLE 5: High-Throughput (HTP) Protein Production

Nicola Burgess-Brown, PhD, Director of Enzymology and Protein Engineering, Exact Sciences Innovation

- Benefits of testing multiple constructs in parallel. How can we produce the full length protein?
- How many and which expression systems should a lab set up to produce a variety of proteins (intracellular, secreted, membrane)?
- HTP expression screening in multiple hosts: What scale, tags, conditions, equipment, readout?
- Challenges of working in HTP: What conditions to test first to increase success?

TABLE 6: Artificial Intelligence and Automation in Bioprocess Development

Peter Herr Neubauer, PhD, Lab Head, Bioprocess Engineering, TU Berlin

- Lab digitalisation how far are we and where are the hurdles?
- How far can we go with automation of experimental approaches in R&D?
- How far can lab automation and model based approaches decrease experiments to save time and costs?
- Where do you see opportunities and limits of AI in bioprocess development?
- What do you think of the value of small scale high throughput experimental approaches for larger scale processes?

15:25 Session Break

AUTOMATION AND PROCESS OPTIMIZATION

15:35 Chairperson's Remarks

James D. Love, PhD, Vice President, Automation & Process Optimization, Novo Nordisk AS

15:40 Expanding the Manufacturing Solution Space: Harnessing Gene Therapy Technology Innovation for Recombinant Protein Production

Adam J. Brown, PhD, Associate Professor, Chemical & Biological Engineering, University of Sheffield

Gene therapy design and manufacturing platforms incorporate many technologies originally created for recombinant protein production. This talk will discuss how this technology flow is now moving in the opposite direction, driven by the innovation required to bring these complex product formats to market. Using recent examples from my academic and industry lab, I will present how we are harnessing our ATMP technological innovations to improve biomanufacturing of DTE protein products.

16:10 Development of an Integrated Messenger RNA Manufacturing Process Using Thermoreversible Aqueous Biphasic Systems

Augusto Q. Pedro, PhD, Researcher, CICECO, Department of Chemistry, University of Aveiro

mRNA vaccines are in the spotlight, creating an opportunity to reinforce the expertise in mRNA manufacturing technologies. Built upon the tunable character of ionic liquids and able to achieve enhanced extractions and keep the stability of nucleic acids, these compounds are being investigated by a CICECO team (Augusto Pedro, Francisca Silva, Mara Freire, Maria Sousa, and Luís Silva) to integrate the production and clarification steps in the mRNA manufacturing process.

16:40 Opportunities and Challenges of Automating High Throughput Protein Purification

Jana Langhoff, Tecan

Time to market is crucial in process development, and many companies developing and manufacturing therapeutic agents have invested in automated protein purification and high throughput bioprocessing. The miniaturization and parallelization capabilities of Tecan's liquid handling platforms ensure an excellent understanding of bioprocesses for robust scale-up into manufacturing, enabling cost-effective development.

16:55 Accelerating biologic development programs with a state-of-the-art CHO expression system

Ana Rebocho, Manager, BioP R&D, Revvity

Revvity's CHOSOURCE™ expression platform is used globally for the development of biotherapeutics. The CHOSOURCE™ platform has been recently improved by the introduction of the CHOSOURCE™ TnT transposon technology. This technology uses transposases to reduce variability and screening efforts, enabling the efficient generation of stable, high producing clones, when compared to traditional Random Integration methods. This technology leads to the safe acceleration of cell line development programs.

8TH ANNUAL | LISBON, PORTUGAL

PROTEIN PROCESS DEVELOPMENT

Optimizing Workflows to Streamline Bioproduction from Benchtop to Manufacturing

17:10 An Integrated Approach for the Process Development and Scale-Up of Recombinant Proteins
Jonathan Jones, Manager, Upstream Microbial, CPI Biologics
Utilising high-throughput systems and an ability to gain a holistic view of both product and process challenges is critical in the process development of modalities such as recombinant proteins. Approaching process development with molecular design, upstream production, downstream purification, and analytical characterisation in a single focused effort can allow for improvements in process understanding and expedite timelines in a product's journey from bench to clinic.

17:40 Using Machine-Learning to Transfer Learnings across Development Stages towards a Digital Platform Process
Miguel Pupo, PhD, Process Modelling Engineer, DataHow AG
Quality by Design is cost-effective only when knowledge is transferred from one drug candidate to the next, from one scale to the other. In this contribution we show how transfer learning methods that originate from the area of machine-learning can be used to transfer knowledge between products and scale, allowing reduction of experimental effort and acceleration of process development.

18:10 FEATURED PRESENTATION: Automation and Closed Loop Optimization of Protein Development Processes
James D. Love, PhD, Vice President, Automation & Process Optimization, Novo Nordisk AS
The combination of digital technologies with automation enables experimentation to enter an era — closing the loop of experimental design together with set up and analysis, and resulting in the self-driving lab. This presentation will demonstrate both hardware and software solutions that have been used to make these physical manifestations of AI, real-world, and the useful application to protein centric development processes.

18:40 Close of PEGS Europe Summit

Training SEMINARS
By Cambridge Healthtech Institute

INTRODUCTION TO MACHINE LEARNING FOR BIOLOGICS DESIGN

INSTRUCTOR:
Christopher R. Corbeil, PhD, Research Officer, Human Health Therapeutics, National Research Council Canada

This course offers an introduction to concepts, strategies, and machine learning methods used for biologics design. It includes presentations and demonstrations of the methods used in the field, covering techniques such as triaging sequences, modulating affinity, and designing antibody libraries, along with increasing manufacturability. The course is directed at scientists new to the field and protein engineers wanting an introduction to how machine learning can aid in guiding biologics design.

SEMINAR HIGHLIGHTS:

- Basics of machine learning and where it fits into drug discovery
- Machine learning: a historical view of its application in the field of drug discovery
- How machine learning revolutionized homology modeling
- Applying machine learning to structure-based biologics design
- Guiding the design of display libraries using machine learning

Christopher R. Corbeil, PhD

Research Officer, Human Health Therapeutics, National Research Council Canada

Dr. Christopher Corbeil is a research officer at the National Research Council Canada (NRC) who specializes in the development and application of computational tools for biotherapeutic design and optimization. He is also an associate member of the McGill Biochemistry Department and teaches classes in Structure-Based Drug Design at McGill University. After receiving his PhD from McGill University, he joined the NRC as a Research Associate investigating the basics of protein-binding affinity. Following his time at the NRC he joined Chemical Computing Group as a research scientist developing tools for protein design, structure prediction, and binding affinity prediction. He then decided to leave private industry and rejoin NRC with a focus on antibody engineering. Dr. Corbeil has authored over 30 scientific articles and is the main developer of multiple software programs.

2ND ANNUAL | LISBON, PORTUGAL

MACHINE LEARNING FOR PROTEIN ENGINEERING - PART 1

De novo Design, Implementation Challenges, and Innovative Models

WEDNESDAY 15 NOVEMBER

7:30 Registration Open and Morning Coffee

DE NOVO DESIGN USE CASES

8:25 Chairperson's Opening Remarks
Tushar Jain, PhD, Principal Scientist, Computational Biology, Adimab LLC

8:30 Lab-in-the-Loop, an ML-Driven Platform for Automated Molecular Discovery and Design
Nathan Frey, PhD, Machine Learning Scientist, Prescient Design, a Genentech Company

We will discuss the "Lab-in-the-loop" system, a collaboration between Prescient Design and Antibody Engineering at Genentech, to build and integrate state-of-the-art machine learning methods with large molecule design and discovery capabilities. Lab-in-the-loop encompasses generative models, pseudo-oracles, physics-based modeling, large language models, wet-lab assays, and active learning to fundamentally change early-stage drug discovery.

9:00 Generation and Experimental Validation of Novel *de novo* Abs with Unique Functionalities
Yanay Ofran, PhD, Founder, CEO, Biolojic Design Ltd.

Most therapeutic antibodies are simple antagonists. However, like all proteins, antibodies can be sophisticated nano-machines. Biolojic Design uses AI to program antibodies to become dynamic functional switches affecting biology in new ways. I will describe our AI-design process, and share clinical data from the first AI-designed therapeutic antibody. I will also show preclinical data on multi-specific antibodies illustrating their potential to improve outcome in cancer and autoimmune diseases.

9:30 Selecting Optimal Antibodies for IND-Enabling Studies with an Integrated High-Throughput & Lead Assessment Platform
Lucas Kraft, Senior Research Scientist, Translational, AbCellera

10:00 Session Break to Transition into Plenary Keynote

PLENARY KEYNOTE SESSION

10:10 Plenary Keynote Introduction
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

10:15 Benchmarking the Impact of AI Biologics Discovery and Optimisation for Pharma
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

At PEGS Europe, we will present current *in silico* biologics design and optimisation technologies, with a focus on our internal efforts to benchmark the impact of combining novel *in silico* technologies with our existing biologics discovery platforms.

10:45 Keynote Chat
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca

10:45 Plenary Fireside Chat
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

11:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:45 Accelerating the Discovery Pipeline with ML: From Library Design to Discovery and Optimization, and Early Developability Screening
Tushar Jain, PhD, Principal Scientist, Computational Biology, Adimab LLC

Incorporating predictive modeling into experimental workflows holds great promise for accelerating discovery, guiding optimization, and prioritizing leads. Here we discuss application of ML to design of synthetic libraries for discovery, hybrid experimental-modeling approaches for selection of functionally diverse antibodies, and developability predictions that decrease resource-intensive experiments. Our integration of ML into a larger informatics/data platform enables predictions to inform candidate selection throughout the discovery and lead optimization process.

12:15 KEYNOTE PRESENTATION: Antibody Structure and Dynamics in Solution
Klaus R. Liedl, PhD, Professor, Head, General, Inorganic, & Theoretical Chemistry, University of Innsbruck

Antibodies are highly flexible molecules, due to the hinge regions, the elbow linkers, the interdomain interfaces between Ig-fold domain pairs and the loops in the paratope. We demonstrated that the binding competent structure is normally the dominant structure in solution, even though it is often not the structure found for unbound antibodies. The resulting opportunities and challenges for AI-driven antibody structure prediction are discussed in the light of these findings.

12:45 Innovative Antibody Discovery Workflow Leveraging Artificial Intelligence to Prioritize Leads
Crystal Richardson, Ph.D, Business Partnership Manager, Azenta Life Sciences

Azenta now offers an innovative end-to-end antibody screening solution that guides your discovery program to more diverse leads while reducing liabilities for antibody development. Utilizing next generation sequencing of your in-vivo samples (i.E. B-cells, pbmcs) or in-vitro libraries (i.E. Phage display), a bioinformatics platform, and gene synthesis, antibodies are produced with promising biophysical profiles for commercialization.

13:15 Session Break

2ND ANNUAL | LISBON, PORTUGAL

MACHINE LEARNING FOR PROTEIN ENGINEERING - PART 1

De novo Design, Implementation Challenges, and Innovative Models

13:20 LUNCHEON PRESENTATION: Smart People Solve Problems. AI Geniuses Avoid Them

Patrick Doonan, Ph.D., Director of Antibody Engineering, Antibody Discovery, XtalPi

XtalPi's comprehensive end-to-end antibody discovery pipeline utilizes an array of unbiased AI checkpoints across every phase of the process. Generative AI and *in silico* prescreening reduces the burden of wet-lab experimentation thereby expediting the time to clinic. Developability concerns are minimized early in the discovery process to avoid problematic leads. Our AI tools are used to further improve quality hits resulting in highly developable antibodies with exceptional therapeutic potential.

14:20 Session Break

IMPLEMENTATION CHALLENGES AND SOLUTIONS

14:30 Chairperson's Remarks

Jeffrey Ruffolo, PhD, Machine Learning Scientist, Profluent Bio

14:35 Developing Internal AI Capabilities via External Collaborations and Internal Resources

Hubert Kettenberger, PhD, Head, Computational Protein Engineering, Roche

AI applications have become increasingly powerful, and play an increasing role in today's research and development. At the same time, there is no consensus yet regarding AI methodologies, and how to best integrate them in the discovery and development process. Building internal capabilities and establishing external collaborations can help navigate through this exciting new augmentation of biologics drug development.

EMERGING MODELS AND PLATFORMS

15:05 Implementation of CamSol Using Machine Learning

Marc Oeller, PhD, Postdoctoral Fellow, Mann Group, Max Planck Institute of Biochemistry

In 2015, we introduced the CamSol method, which enables accurate prediction of protein solubility solely by analysing the physico-chemical properties of their sequences. We recently extended the method to enable accurate prediction of non-natural amino acids such as chemically or posttranslationally modified ones. In this talk, I will highlight how CamSol can be used in drug development pipelines and explore the possibilities to extend CamSol using machine learning.

15:35 AI Driven *de novo* Antibody Discovery

Satoshi Tamaki, PhD, CSO, MOLCURE Inc.

Considering the challenges of antibody development, MOLCURE has designed a platform that integrates AI, robotics, and molecular biology experiments. Our platform has generated >1 billion data points to train AI models. We would like to introduce the showcase of the discovery of pM-order affinity VHH antibody from a single phage display experiment and discuss the future that generative AI opens up.

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 FEATURED PRESENTATION: Generative Antibody Modelling

Charlotte M. Deane, PhD, Professor, Structural Bioinformatics, Statistics, University of Oxford; Chief Scientist, Biologics AI, Exscientia

Here we show that by optimising an inverse folding model specifically for antibody structures, we are able to outperform generic protein models on sequence recovery and structure robustness, with notable improvement on the hypervariable CDR-H3 loop.We also demonstrate the applications of our model to drug-discovery and binder design and evaluate the quality of proposed sequences.

17:30 Integration of Machine Learning, Structural Biology, and Wet Lab Data to Augment Drug Discovery for Autoimmune Diseases

Nathan Higginson-Scott, PhD, CTO, Seismic Therapeutic

We will discuss how Seismic Therapeutic is using its IMPACT platform to integrate machine learning, structural biology, protein engineering and translational Immunology to accelerate the discovery and development of therapeutics for autoimmune diseases, caused by a dysregulated adaptive immune system.

18:00 Machine Learning for Biomolecule Engineering

Anna Puszkarska, PhD, Senior Machine Learning Scientist, Biologics Engineering, AstraZeneca

Engineering new biological molecules with desired activity profiles requires time consuming and expensive cycles of design-make-test-analyse (DMTA) work. Even for short protein sequences, the available exploration space is intractable for traditional methods of experimental biology. In this talk, I will discuss how machine learning can be used to augment the design of peptide therapeutics. Specifically, I will present our recent studies focussed on *de novo* design and optimisation of GPCR ligands.

18:30 Generative Modeling for Functional Protein Design

Jeffrey Ruffolo, PhD, Machine Learning Scientist, Profluent Bio

Generative language models trained on protein sequences have proven incredibly powerful for protein sequence design. In this talk, we will demonstrate how protein language models enable discovery of diverse proteins, which often function on par with natural counterparts- despite significant deviation in sequence space. Beyond generation of sequences, protein language models are effective zero-shot predictors of fitness, enabling direct optimization of function.

19:00 Close of Machine Learning for Protein Engineering – Part 1 Conference

2ND ANNUAL | LISBON, PORTUGAL

MACHINE LEARNING FOR PROTEIN ENGINEERING - PART 2

Demonstrating Value and Putting Theory into Practice

THURSDAY 16 NOVEMBER

7:30 Registration Open and Morning Coffee

PLM AND GENERATIVE MODELING FOR *DE NOVO* DESIGN

8:55 Chairperson's Remarks
Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo

9:00 Enhancing Antibody Discovery with Generative AI
Melody Shahsavarian, PhD, Digital Biologics Platform, Large Molecules Research, Sanofi
With a growing majority of its pipeline composed of biologics, there is an increasing need at Sanofi to bring more molecules to development at a faster pace. Generative AI and *in silico* screening methods provide opportunities to improve probability of success and decrease discovery-to-lead timelines. Combining deep repertoire mining technologies and generative ML modeling, we are building a *de novo* protein design platform and a more targeted drug discovery approach.

9:30 The Singular Immune Response to Dengue and Machine Learning Identification of Antibodies in High-Throughput Sequences
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET
Dengue virus is a threat to global health. However, no specific therapeutics are available so far. Broadly neutralizing antibodies recognizing the various serotypes could serve as potential treatment. High-throughput adaptive immune receptor repertoire high-throughput sequencing (AIRR-seq) and bioinformatic analyses enable in-depth understanding of the B cell immune response.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Protein Engineering with Large Language Models
Ali Madani, PhD, Founder and CEO, Profluent Bio
Generative models have shown promise in capturing the distribution of natural proteins. In this talk, we'll cover a research evolutionary trajectory of the application of large language models from natural language processing to functional protein design. We'll conclude with a look into future scaling and preliminary trends.

11:15 Computational Counterselection Identifies Nonspecific Therapeutic Biologic Candidates
Stefan Ewert, PhD, Associate Director, Biologics Center, Novartis Institutes for Biomedical Research
Biologics require high specificity for targets, but current affinity-selection-based discovery methods do not guarantee this property. We present a method, computational counterselection, that identifies nonspecific candidates using machine learning models of affinity trained on high-throughput data from single-target affinity selection experiments.

11:45 Applying Deep Learning Anomaly Detection to Antibody Structures
Hiroki Shirai, PhD, Coordinator, RIKEN Center for Computational Science
How to mitigate risks of antibody sequences especially generated with AI? Most of the methods for human-ness evaluation have a limitation due to the presence of V-D-J faults. We developed a method to evaluate human-ness from 2D pixel images of antibody structures using CNN-VAE, which is a technique used to detect outliers in factory-produced products. We also introduce a new method to improve conformational stability with a single mutation.

12:15 Computational Nanobody Binding Epitope prediction and Re-epitoping
Anne Goupil-Lamy, PhD, Science Council Fellow at BIOVIA, BIOVIA, Dassault Systèmes
Discover how molecular modeling and deep learning are transforming nanobody epitope mapping and re-epitoping, advancing precision antibody engineering for diverse applications in biotechnology and medicine.

12:45 Enjoy Lunch on Your Own

13:50 Dessert Break in the Exhibit Hall & Last Chance for Poster Viewing

14:45 Session Break

STRUCTURE, DOCKING, AND DYNAMICS FUNDAMENTALS

15:00 Chairperson's Remarks
Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo

15:05 Unconstrained Generation of Synthetic Antibody-Antigen Structures to Guide Machine Learning Methodology for Antibody Specificity Prediction
Rahmad Akbar, PhD, Researcher, Computational Systems Immunology, University of Oslo
Antibody structures inform and improve machine learning predictions. We devise a method for the parameter-based unconstrained generation of synthetic lattice-based three-dimensional antibody-antigen-binding structures. Our method provides ground-truth access to conformational paratope, epitope, and affinity. We showcase the utility of synthetic datasets to benchmark the real-world relevance of machine learning models for antibody binding prediction.

15:35 Third-Generation Approaches of Antibody Discovery and Optimisation
Pietro Sormanni, PhD, Group Leader, Royal Society University Research Fellow, Chemistry of Health, Yusuf Hamied Department of Chemistry, University of Cambridge
I will discuss emerging computational antibody design methods, which enable the targeted design of antibodies for predetermined epitopes and the prediction and modulation of their developability potential through the co-optimization of multiple biophysical properties. Overall, it is increasingly possible to complement well-established *in vivo* (first-generation) and *in vitro* (second-generation) methods of antibody discovery with *in silico* (third-generation) approaches, with time- and cost-saving benefits.

2ND ANNUAL | LISBON, PORTUGAL

MACHINE LEARNING FOR PROTEIN ENGINEERING - PART 2

Demonstrating Value and Putting Theory into Practice

NOVEL/ALTERNATIVE ML-ENABLED SCREENING TECHNOLOGIES FOR HIGHER POS

16:04 Chairperson's Remarks
M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, Inc.

16:05 scifAI: An Explainable Machine Learning Framework Applied to Functional Characterization of Therapeutic Antibodies
Fabian Schmich, PhD, Senior Data Scientist, pRED Informatics, Roche Diagnostics Deutschland GmbH
scifAI is a comprehensive, open-source explainable machine learning framework for the analysis of imaging flow cytometry data. In this presentation, I will focus on alterations to the immunological synapse, analyzing class frequency- and morphological changes of the cell, as well as showcasing the prediction of T cell cytokine production under stimulation with different antibodies, linking morphological features with function and thus demonstrating the potential to significantly impact antibody design.

16:35 Accelerating Antibody Development: Advancing Discovery through Integrated Bioinformatics and Machine Learning PipeBio
Jannick Bendtsen, CEO, PipeBio
Early-stage antibody discovery requires efficient and comprehensive approaches to identify promising candidates with optimal developability characteristics. This presentation explores how next-generation sequencing (NGS) analysis and machine learning can be applied to optimize antibody developability. We explore a practical implementation of analysis pipelines using PipeBio Bioinformatics Platform and illustrate the benefits of applying such analysis tools through case studies, showing their efficacy in expediting early-stage antibody discovery.

16:50 Low-Data Interpretable Deep Learning Prediction of Antibody Viscosity Using a Biophysically Meaningful Representation
Brajesh K. Rai, PhD, Senior Director, Machine Learning Computational Sciences, Pfizer Inc.
Deep learning has led to substantial advances across many disciplines. However, many scientific problems of practical interest lack sufficiently large datasets amenable to deep learning. Prediction of antibody viscosity is one such problem where these methods have not yet been explored due to the relative scarcity of relevant training data. We will describe how we have overcome this limitation using a biophysically meaningful representation to develop generalizable deep learning models.

17:20 Integrating Single-Cell Immune Repertoire Sequencing, Machine Learning, and Biophysical Properties of Antibodies
Alexander Yermanos, PhD, Lecturer, Systems & Synthetic Immunology, ETH Zurich
Immune repertoires represent a diverse collection of B and T cell receptors which interact with a seemingly infinite number of molecular structures. Recent advancements in deep sequencing and microfluidics allow high-throughput recovery of paired heavy- and light-chain sequences, thereby linking computational features of immune repertoires to biophysical properties of antibodies at an unprecedented resolution. I will explore the intersection of repertoires, ML, and biophysical features like antigen-specificity, affinity, and epitope.

17:50 PANEL DISCUSSION: Current State of AI in Antibody Therapeutics: The Promise, the Reality and the Hype
Co-Moderators:
M. Frank Erasmus, PhD, Head, Bioinformatics, Specifica, Inc.
Victor Greiff, PhD, Associate Professor, Immunology, University of Oslo
Panelists:
Andrew R.M. Bradbury, PhD, CSO, Specifica, Inc.
Rebecca Croasdale-Wood, PhD, Director, Augmented Biologics Discovery & Design, Biologics Engineering, Oncology, AstraZeneca
René M.A. Hoet, PhD, Chief Innovation Officer, FairJourney Biologics
Enkelejda Miho, PhD, Professor, University of Applied Sciences and Arts Northwestern Switzerland, and Managing Director, aiNET

18:30 Close of PEGS Europe Summit

"The best biologics technology meeting in Europe: a must-attend conference for novel biologics."
Rakesh D., PhD, President & CEO, Bionavigen

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Hotel & Travel Information

CONFERENCE VENUE:

Lisbon Congress Center
Pracas Das Industrias
Lisbon, 1300-307, Portugal

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Monday 13 November | 14:00 – 17:00
SC1: Machine Learning Tools for Protein Engineering
SC2: Developability of Bispecific Antibodies: Formats and Applications
~~SC3: The Tumour Microenvironment and Response to Cancer Immunotherapy~~
SC4: The Use and Optimization of Eukaryotic Expression Systems to Support Therapeutic Generation and Structural Biology
SC5: Best Practices for Targeting GPCRs, Ion Channels, and Transporters with Monoclonal Antibodies

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	Tuesday 14 November	Wednesday 15 November	Thursday 16 November
ENGINEERING	C1A: Display of Biologics	C1B: Engineering Antibodies	C1C: Machine Learning for Protein Engineering - Part 2
TARGETS	C2A: Antibody-Based Cancer Therapies	C2B: Emerging Targets and Therapeutic Approaches	C2C: Antibodies Against Membrane Protein Targets
BISPECIFICS	C3A: Safety & Efficacy of Bispecific Antibodies	C3B: Advancing Bispecifics and Combination Therapy to the Clinic	C3C: Engineering Bispecific Antibodies
IMMUNOTHERAPY	C4A: Modulating the Tumour Microenvironment	C4B: Innovations in CAR T Therapy and Engineering *in vivo* Solutions	C4C: Next-Generation Immunotherapies
ANALYTICAL	C5A: Optimisation & Developability	C5B: Analytical Characterisation of Biotherapeutics	C5C: Protein Stability & Formulation
EXPRESSION	C6A: Cell Line and Systems Engineering	C6B: Optimising Expression Platforms	C6C: Protein Process Development
MACHINE LEARNING	TS7A: IN-PERSON ONLY Introduction to Machine Learning for Biologics Design	C7B: Machine Learning for Protein Engineering - Part 1	C7C: Machine Learning for Protein Engineering - Part 2
TRAINING SEMINARS	TS8A: IN-PERSON ONLY Introduction to Bispecific Antibodies: History, Engineering, and Application OR TS9A: IN-PERSON ONLY Introduction to Protein Engineering		

** Pre-doctoral, full-time student*

See website for details on Group discounts and On-Demand options

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