Global Engage

GLOBAL ENGAGE'S 3RD

BIOLOGICS & BIOSIMILARS CONGRESS 2017

BERLIN, GERMANY

6-7 March 2017

Examining Scientific, Technological & Business Trends to Advance Protein & Antibody Therapeutics

www.global-engage.com/event/biologics/

#GEBB17

WARM WELCOME

Global Engage

Thank you for your interest in the **3rd Global Engage Biologics and Biosimilars Congress**, which will be held on March 6-7, 2017 in Berlin, Germany. Providing an opportunity to network with senior representatives of leading pharmaceutical and biotech companies, this well received event attracted 200 attendees in 2016.

Attracting industry, regulatory & academic experts working in all areas of protein, antibody & biosimilar research this two-day interactive meeting will explore a variety of topics across three streams. The first stream focuses on the latest innovations in antibody based therapeutics, leaders from the industry will be presenting updates on their strategy, pipeline and exciting candidates. The second stream includes presentations on expression, purification and characterisation, discussing issues around stability and half-life, as well as presenting novel cancer therapy approaches. The Biosimilars stream explores themes of similarity, regulation and public perception, alongside presentations on candidate generics in various stages of development. Executive panels and roundtables will foster discussion on the direction of the field, and the approaches required to ensure that the industry continues to flourish.

EXPERT SPEAKERS Include:

MARIE KOSCO-VILBOIS
Chief Scientific Officer,
NovImmune SA

RALF SCHUMACHER
Global Head of Bioprocess and Pharmaceuticals Development,
Boehringer Ingelheim

ANDREA HAWE
Chief Scientific Officer,
Coriolis Pharma

RICHARD GREGORY
Chief Scientific Officer,
ImmunoGen Inc

CONFERENCE SYNOPSIS

ANTIBODY BASED THERAPEUTICS

- Antibody discovery & optimization
  - Monoclonal antibodies
  - Recombinant antibodies
- Overcoming safety and risks
- Antibody mixtures

- Antibody-drug conjugates – development, potential & challenges
  - Optimising ADC stability & potency
  - Optimizing payloads & linkers
  - Site specific ADCs
  - ADC design

- Cancer Immunotherapy
  - T cell therapy
  - Chimeric antigen receptors (CARS)
  - Immune Checkpoint Blockades
  - Bispecific antibodies

PROTEIN BIOTHERAPEUTICS

- Overcoming immunogenicity and aggregation issues
- Alternative scaffolds
- Half-life extension
- Fusion proteins

- Protein Expression, Purification & Characterisation
  - Examining different expression systems/technologies
  - Strategies to improve expression, purification, increase yields and enhance protein development
  - Difficult proteins
  - Characterization processes
  - HCP analysis
  - Cell line development

BIOSIMILARS

- Development Strategy, Market Access and Commercialization
  - Developing a successful global biosimilars development strategy
  - Physician & patient attitudes
  - Strategies to successfully commercialize biosimilars products in Europe, USA and Emerging markets
  - Overcoming market access and commercialization barriers
  - Pricing & Reimbursement value
  - IP
  - Case Study examples

- Development Strategy, Market Access and Commercialization
  - Current worldwide regulatory issues, updates & guidelines to obtain approval
  - Quality and CMC considerations for biosimilar development
  - Dealing with immunogenicity
  - Demonstrating biosimilarity
  - Optimising biosimilar clinical trial design
  - Successful Biosimilar drug case study examples

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CONFIRMED SPEAKERS

RONALD HERBST
Vice President of Oncology Research, MedImmune

RALF SCHUMACHER
Global Head of Bioprocess and Pharmaceuticals Development, Boehringer Ingelheim

MARTIN STEEGMAIER
Head of Discovery, Large Molecule Research, Roche

MARIE KOSCO-VILBOIS
Chief Scientific Officer, NovImmune SA

NICOLAS POIRIER
R&D Director, OSE Immunotherapeutics

SVETLANA SADEKOVA
Group Leader, Experimental Pathology, Merck Sharp & Dohme

HANS HENNING VON HORSTEN
Professor, Industrial Biomanufacturing, HTW- Berlin University of Applied Sciences

JENS LOHRMANN
Senior Global Programme Manager, Novartis

ANDREA HAWE
Chief Scientific Officer, Coriolis Pharma

LAURA LIN
Senior Director, Global BioTherepeutic Technologies, Pfizer

ARNE SKERRA
Professor, Technische Universitat, Munchen & Chief Scientific Officer XL Protein GmbH

ANDREAS PAHL
Chief Scientific Officer, Heidelberg Pharma Gmbh

SALVADOR VENTURA
Chair Professor of Biochemistry and Molecular Biology, Universitat Autonoma de Barcelona

JULIA NEUGEBAUER
Associate Director, Morphosys

MARINE RAMAN
Senior Scientist, Protein Science, Immunocore

PIETER FOKKO VAN LOO
Director, Merus N.V.,

ANGELA NEUBAUER
Head of Product Development, BIOMAY AG

MARTIN SIEGEMUND
University of Stuttgart

JENS WUERTHNER
Assistant Vice President, ADC Therapeutics

MARINA PAVLIDOU
Group Leader Selection Technologies, Pieris

LUKE MASTERSON
Chemistry Group Leader, Spirogen

SYD JOHNSON
VP Antibody Engineering, Macrogenics

PETR OBRDLIK
Fellow, Novartis

RICHARD GREGORY
Chief Scientific Officer, ImmunoGen Inc

ALEXANDER GOLOVANOV
Senior Lecturer, Manchester Institute of Biotechnology and School of Chemistry, University of Manchester

LUIS BORLIDO
Lab Head, Physico-Chemical Characterisation, Sandoz

BART VAN DEN BEMT
Head, Department of Pharmacy, Radboud University

BALAZS VEZER
International Marketing Manager, EGIS Biologicals

ALEX KUDRIN
Biopharmaceutical Consultant

UWE GUDAT
Head of Safety, Biosimilars, Merck Serono

YELENA BISHARYAN
Director of External Alliances, Tetragenetics

MIHRIBAN TUNA
Vice President Discovery, F-star

YUJI KASUYA
Senior Scientist, Kitasato Daiichi Sankyo Vaccine Co., Ltd, Japan

SANDEEP ATHALYE
Vice President and Head, CDMA, Biosimilars, Boehringer Ingelheim

GRAHAM FOXON
Managing Director, ReMAP Consulting

VOLKER SCHELLENBERGER
President and CEO, Amunix

CONFIRMED SPEAKERS

STEFFEN NOCK
Senior Vice President (Global Biologics Head), Teva Pharmaceutical Industries

MOURAD FAROUK REZK
Global Head Medical Affairs, (Biosimilars) Biogen

JANKO BRAND
Senior Scientist, Biotez

DAVID MEININGER
PhD, MBA; Chief Business Officer, TRIANNI, Inc.

OLIVER HILL
VP Molecular Biology, Apogenix

AUBIN MICHALON
Senior Research Scientist, Project Leader Rare Diseases, Neurimmune

NATALIA MARKOVA
Principal Scientist – MicroCal, Malvern Instruments

KARL ANDERSON
PhD, CEO, Ridgeview

PAUL CALVO
Director, Sterne, Kessler, Goldstein & Fox P.L.L.C.

GUIDO SEIDEL
Managing Director Operations, Wacker

GALAHAD DEPERALTA
(Track Chair)
Senior Scientist, Protein Analytical Chemistry, Genentech

JOACHIM KOCH
Project Leader, Affimed

PHILIPP HESS
Managing Director, Philipp Hess Associates

STEFAN ARNOLD
Managing Director, BPC Arnold GmbH BioPharma Consulting

ALEXANDER BAUMANN
Senior Director, Screening & Profiling Services Region Europe, DiscoverX

MATTHEW TURNER
Global Medical Director, Merck Group

DAVID PEARLMAN
Director, Biologics Software Platform and Senior Scientist, Schrödinger GmbH

DAVID RABUKA
(Track Chair)
Global Head of R&D, Chemical Biology, Catalent Pharma Solutions

JOHN GUNN
Ph.D., Senior Research Scientist, Chemical Computing Group

08:00-08:50 Registration & Refreshments

08:50-09:00 **Global Engage Welcome Address & Opening Track Chair's Remarks**

BIOLOGICS CONGRESS

09:00-09:35

KEYNOTE ADDRESS:
RALF SCHUMACHER
Global Head of Bioprocess and Pharmaceuticals Development, Boehringer Ingelheim
Biologics: How to translate Biology understanding in process development?

09:35-10:10

KEYNOTE ADDRESS:
RONALD HERBST
Vice President of Oncology Research, MedImmune
Immunotherapy for Cancer: Beyond Checkpoint Inhibition
Immune-evasion is a hallmarks of cancer and enhancement of the anti-cancer immune response by targeting checkpoint pathways, such as CTLA-4 and PD-1/PD-L1, with monoclonal antibodies are showing significant promise. Combinations of checkpoint therapies have already increased response rates in certain indications. However, a significant subset of patients still fails to benefit from current immune therapies. Going forward it will be key to better understand the immunologic diversity within and across indications, and to develop new combination therapies, based on science, to broaden and deepen the response of cancer patients to immunotherapy.

BIOSIMILARS CONGRESS

09:35-10:10

Reserved

SENIOR REPRESENTATIVE
Pfizer

ANTIBODY BASED THERAPEUTICS

10:10-10:40

SOLUTION PROVIDER PRESENTATION

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PROTEIN EXPRESSION, PURIFICATION & CHARACTERISATION

TRACK CHAIR:
GALAHAD DEPERALTA
Senior Scientist, Protein Analytical Chemistry, Genentech

10:10-10:40

SOLUTION PROVIDER PRESENTATION:

OXFORD GENETICS

BIOSIMILARS CONGRESS

10:10-10:40

SOLUTION PROVIDER PRESENTATION

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10:40-11:40 Morning Refreshments / Poster Presentation Sessions / One to One Partnering Meetings

ANTIBODY BASED THERAPEUTICS

11:40-12:05

MARTIN STEEGMAIER

Head of Discovery, Large Molecule Research, Roche

From format to function – Transformative antibody therapeutics at Roche

- The CrossMAb technology has proven to be very versatile, allowing the generation of various bispecific antibody formats ranging from heterodimeric/asymmetric bivalent 1+1 CrossMAbs to more complex tri- (2+1), tetravalent (2+2) bispecific and multispecific antibody formats.
- These diverse formats provide great opportunity to tackle novel biology and to convey novel mode of actions.
- Examples given will include new bispecific molecules for cancer immunotherapy, ophthalmology indications and the use of novel targeting approaches to treat neurological disorders.

12:05-12:30

AUBIN MICHALON

Senior Research Scientist, Project Leader Rare Diseases, Neurimmune

Conformation-specific antibodies for the treatment of amyloid diseases

- Amyloid formation and efficacy of immunotherapies for the removal of amyloid plaques in patients
- Transthyretin amyloidosis is causing cardiomyopathy and polyneuropathy
- Conformation specific antibody against transthyretin amyloid is triggering remediation of cardiac amyloid

PROTEIN EXPRESSION, PURIFICATION & CHARACTERISATION

11:40-12:05

HANS HENNING VON HORSTEN

Professor, Industrial Biomanufacturing, HTW-Berlin University of Applied Sciences

Designing affinity ligands for downstream process intensification

Biomanufacturing processes generate ever higher product titers in shorter periods of time. In order to fully utilize these dramatic increases in upstream efficiency and productivity, it is essential that downstream production turnover is accelerated and adjusted to this progress. This process intensification is addressed by providing chromatography resins with higher capacity, in-line buffer preparation as well as by continuous automated column operation and directly connected steps without hold time. This increasing need for process intensification requires affinity ligands that allow for higher resin capacities and show a stronger suitability for continuous automated operation. Here we present the development of technologies and strategies for improved affinity capture in an intensified downstream process setting.

12:05-12:30

OLIVER HILL

VP Molecular Biology, Apogenix

Hexavalent single-chain GITRL-Fc fusion proteins: Engineering concept and initial characterization

Based on the Apogenix HERA technology platform, we have created three variants of a fully human hexavalent GITRL-Fc fusion protein intended for T-cell costimulatory approaches in cancer immunotherapy. Minor modifications led to three drug candidates with unique pharmacokinetic properties as explored in mice. We will present the molecular engineering concept and the current results obtained.

BIOSIMILARS CONGRESS

11:40-12:05

LUIS BORLIDO

Lab Head, Physico-Chemical Characterisation, Sandoz

GP2015 (Erelzi™) – Structure-Function relationship as a cornerstone for biosimilarity assessment

In August 2016, the Food and Drug Administration (FDA) approved Sandoz's Erelzi™ as a biosimilar to the reference product Enbrel® (etanercept) in the United States. This talk highlights the importance of establishing and in-depth knowledge of the structure-function relationship for a successful biosimilarity assessment. Furthermore, it presents the challenges created from the manufacturing changes of the reference product in the statistical assessment.

12:05-12:30

MOURAD FAROUK REZK

Global Head Medical Affairs, (Biosimilars) Biogen

12:30-12:45

15 MINUTE SOLUTION PROVIDER PRESENTATION:

JANKO BRAND

Senior Scientist, Biotez

Improved dose decision with comprehensive diagnostics data

Objectives

- To improve adalimumab dosage decision in patients with active Rheumatoid Arthritis (RA) the recoveryELISA technology was used.

Methods

- Seventeen RA patients treated with standard or additional adalimumab injection (boost) were examined during 14 days.

Results

- Boost in combination with diagnostics can clarify the mismatch between clinical presentation and the DAS28. Drug-antigen interaction measurements such as TNF α-neutralization values show differences in the drug-reserve in patient within the therapeutic window (47%) and patients in the sub-therapeutic level (35%). For these pateints adalimumab bioavailability is more important than the presence of adalimumab auto antibodies, furthermore boost is recommended due to lack of predictive biomarkers.

Conclusion

- We show that diagnostic methods help monitor individualized adalimumab dose adjustments to improved patient outcome.

12:45-13:00

SOLUTION PROVIDER PRESENTATION

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12:30-13:00

SOLUTION PROVIDER PRESENTATION:

NATALIA MARKOVA

Principal Scientist – MicroCal, Malvern Instruments

The versatility of Differential Scanning Calorimetry (DSC) in the analytical development of biotherapeutics

Due to the complex nature of proteins, biophysical tools are important in the complete characterization of a biopharmaceutical product. There are several biophysical tools used to assess protein stability, including (but not limited to) circular dichroism (CD), dynamic and static light scattering (DLS and SLS), size exclusion chromatography–multi-angle light scattering (SEC-MALS), Fourier transform infrared spectroscopy (FTIR), analytical ultrafiltration (AUC), size exclusion chromatography (SEC), differential scanning fluorescence (DSF), intrinsic fluorescence (IF) and differential scanning calorimetry (DSC).

Whilst each of these biophysical assays plays an important role, characterizing thermal stability by DSC is critical and widely applied throughout the development pipeline.

Among the main advantages of DSC are:

- DSC is a truly universal and generic assay with direct readout
- DSC is information-rich (multiple descriptors of thermal unfolding), enabling reliable data interpretation for protein characterization and stability screening
- DSC thermograms are sample-specific, quantitative and highly reproducible, making the technology well-suited for protein "fingerprinting"

Due to its versatile nature, DSC has multiple uses throughout stability profiling, formulation development, manufacturing support, and biopharmaceutical comparability and biosimilarity analysis. DSC also supports protein higher order structure (HOS) characterization, which is increasingly becoming expected in regulatory submissions for new biopharmaceutical drugs and biosimilars.

This presentation will contain case study examples of the use of DSC at different stages in the biologic development pipeline.

12:30-13:00

SOLUTION PROVIDER PRESENTATION

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13:00-14:00 Lunch / One to One Partnering Meetings

14:00-14:50

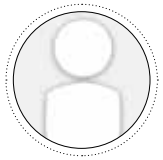
50 MINUTE EXECUTIVE PANEL DISCUSSION:

Developing Antibody based therapeutics

Featuring senior executives from a number of prominent organisations, drawing on the experience and insights of leaders within the field, this panel will discuss the challenges and promise of antibody based therapeutics.

PANELLIST:
STEFFEN NOCK
Senior Vice President (Global Biologics Head), Teva Pharmaceutical Industries

MOURAD FAROUK REZK
Global Head Medical Affairs, (Biosimilars) Biogen



PHILIPP HESS
Managing Director, Philipp Hess Associates

Senior Representatives x2

14:00-14:25

ANDREA HAWE
Chief Scientific Officer, Coriolis Pharma

Impact of nanoparticle impurities from sugar excipients on monoclonal antibody stability

Pharmaceutcial grade sugars (e.g. sucrose) compose particulate impurities that pose an analytical challenge and may compromise the stability, safety and efficacy of protein pharmaceuticals. The nature of nanoparticulate impurities in commonly used sucrose was elucidated by FTIR microscopy, SEM-EDX, fluorescence spectroscopy and mass spectrometry. Within the talk recent data proofing a destabilizing effect of these impurities on the stability of four monoclonal antibodies with respect to aggregation, particle formation and fragmentation will be shown.

14:25-14:50

LAURA LIN
Senior Director, BioMedicine Design, Pfizer Worldwide Research & Development

Early Stage Developability Assessment to Guide the Design and Optimization of High Quality Antibody Leads

The presentation will describe an early stage developability platform we established in-house to rank, select, and optimize antibody leads in early discovery at Pfizer. I will be discussing our strategies of early screening for optimal physicochemical properties and platform process assessment for projects, sharing several case studies highlighting the impact of such assessment on antibody optimization strategies, and predictability of early screens on efficacy, PK, and manufacturability.

14:00-14:50

BALAZS VEZER
International Marketing Manager EGIS Biologicals

Biosimilar mAb awareness – Communication challenges

While biopharmaceutical medicines have been available for more than 30 years, many type of biosimilars gained European approvals in the last 10 years.

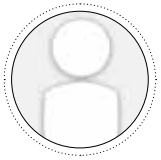
The Celltrion developed biosimilar infliximab (Remsima) become the first EMA approved mAb biosimilar in 2013.

The complex structured monoclonal antibody biosimilar have faced new concerns on the market. The chance of their acceptance and success are depend of an effective communication strategy.

Based on real life experience of Remsima launch in Egis region I will summarize the communication strategy development in main topics as:

- Biosimilars development paradigm
- Biologicals variability and related regulatory authority experience of their variability
- Indication extrapolation
- Interchangeability

14:25



BART VAN DEN BEMT
Head, Department of Pharmacy, Radboud University

Title TBC

14:50-15:15

SVETLANA SADEKOVA

Group Leader, Experimental Pathology, Merck Sharp & Dohme

Characterization of MK-4166, an agonistic mAb that targets human GITR

GITR, a member of the TNFR superfamily, provides co-stimulatory signals to T cells leading to enhanced cellular and humoral immunity. To explore the potential utility of GITR agonists in cancer immunotherapy, we developed MK-4166, a humanized agonist monoclonal antibody against human GITR. Since very little is known about the function of human GITR compared to its mouse ortholog, we focused on characterizing the expression of GITR in human tumors and blood and used MK-4166 to investigate the potential role of GITR agonism in human anti-tumor immune responses. GITR expression and ex vivo functional activity of MK-4166 which is currently being evaluated in a Phase 1 clinical trial will be discussed.

14:50-15:15

ARNE SKERRA

Professor, Technische Universitat, Munchen & Chief Scientific Officer XL Protein GmbH

PASylation®: the biological alternative to PEGylation for plasma half-life extension and beyond

Fusion of proteins or peptides with conformationally disordered polypeptides comprising the L-amino acids Pro, Ala, and/or Ser (PAS) is a beneficial way to enlarge the hydrodynamic volume and retard kidney clearance, a common drawback in biological drug development. PAS sequences are strongly hydrophilic, yet uncharged biological polymers with biophysical properties surprisingly similar to PEG though, in contrast, they allow traceless metabolization. Besides chemical coupling, PAS polypeptides offer simple attachment to a biological drug at the genetic level and they can serve as convenient spacers for the design of bispecific fusion proteins. PASylation has been successfully applied to a series of biopharmaceuticals, including interferon, leptin, enzymes, lipocalins and Fab fragments, yielding several drug candidates currently on the route towards clinical study.

14:50-15:15

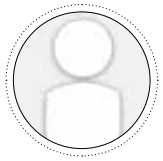
ALEX KUDRIN

Biopharmaceutical Consultant

Global perspectives on evolution of the biosimilars market

- The presentation will focus on brief overview of the current regulatory status and imminent developments in regulated territories
- Regulatory and development challenges for biosimilars
- Future prospects and areas of growth

15:15-15:45



SOLUTION PROVIDER PRESENTATION:

MaxCyte

15:15-15:45

SOLUTION PROVIDER PRESENTATION: KARL ANDERSSON

PhD, CEO, Ridgeview

Time-resolved interaction analysis on living cells: Comprehensive data generates new knowledge and better decisions

- Enabling precise interaction analysis of biologicals and bispecifics interacting with cell-surface receptors on living cells with LigandTracer
- Using detailed binding data to decipher underlying biology and support mode of action determinations
- Selecting binders based on clear and highly repeatable binding characteristics obtained relevant, cell-based environment

ridgeview instruments ab

15:15-15:45

SOLUTION PROVIDER PRESENTATION

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15:45-16:35 Afternoon Refreshments / One to One Partnering Meetings / Poster Presentation Sessions

16:35-17:00

ANDREAS PAHL

Chief Scientific Officer, Heidelberg Pharma Gmbh

Amanitin-based antibody-drug-conjugates as new therapeutic modalities for cancer therapy

Antibody-drug-conjugates (ADCs) combine the well-established principle of targeted antibodies (safety and tolerability) with the effectiveness of ultrapotent toxins (anti-tumor efficacy). The function of the antibody of the ADC molecule is ´to guide´ the toxin specifically to the target tumor cells, and to keep healthy cells unaffected. Antigen-Targeted Amanitin-Conjugates (ATACs) represent a new class of ADCs using a toxin with a novel mode of action, inhibition of RNA pol II. The high potency of this toxin leads to highly efficacious ADCs. Here we present the development of this technology and strategies to achieve a therapeutic index making this technology applicable for cancer therapy. Preclinical data of a BCMA-ATAC will be presented which lead to the start of the clinical development of this first ATAC.

16:35-17:00

SALVADOR VENTURA

Chair Professor of Biochemistry and Molecular Biology, Universitat Autonoma de Barcelona

Designing protein soluability

One of the major challenges that one should face during the development of protein-based biopharmaceuticals is their inherent propensity to aggregate. Indeed, protein therapeutic agents are both stored and typically administered at very high concentrations. Under these conditions they can easily aggregate, impacting the product's developability, stability, formulation, and immunogenicity. I will discuss how computationally-assisted design of protein structures solubility is helping us to overcome these limitations.

16:35-17:00

UWE GUDAT

Head of Safety, Biosimilars, Merck Serono

17:00-17:30

SOLUTION PROVIDER PRESENTATION: DAVID MEININGER

PhD, MBA; Chief Business Officer, TRIANNI, Inc.

The Trianni Mouse: Best-In-Class Technology for Human Antibody Discovery

The Trianni Mouse is the only human transgenic antibody discovery platform offering a complete heavy, kappa and lambda repertoire in a single organism. Sequences of the variable domain exons are human while all genetic machinery including extensively optimized promoters and enhancers are of mouse origin. Titers and class switching are extremely robust making for highly efficient lead generation. This next-generation technology is seen as best-in-class by multiple Big Pharma and other licensees subsequent to extensive validation and benchmarking. Additional strains in development include Plasma Ig, Autoimmune/All Epitope and a "true" Bispecific.

TRIANNI

17:00-17:30

SOLUTION PROVIDER PRESENTATION: GUIDO SEIDEL

Managing Director Operations, Wacker

New solutions for production of difficult-to-express proteins

Wacker Biotech will present highly competitive solutions for production of difficult-to-express proteins based on its proprietary E. coli expression systems ESETEC® and FOLDTEC®. Recent case studies will include secretion of functional antibody fragments and enzymes to the fermentation broth with up to 14 g/L. Together with its E. coli refolding platform FOLDTEC®, Wacker Biotech offers a novel and comprehensive approach to rapidly assess manufacturability of therapeutic proteins.

WACKER

17:00-17:30

SOLUTION PROVIDER PRESENTATION

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17:30-17:55

JULIA NEUGEBAUER

Associate Director, Morphosys

Antibodies targeting peptide/HLA complexes for cancer therapy

17:55-18:20

PIETER FOKKO VAN LOO

Director, Merus N.V., The Netherlands

MCLA-117, a CLEC12AXCD3 bispecific IGG targeting a leukemic stem cell antigen, induces t cell mediated AML blast lysis

Patients with acute myeloid leukemia (AML) have a dismal prognosis despite improvements in chemotherapy and supportive care. We have developed MCLA-117, a CLEC12AxCD3 bispecific human IgG1 antibody for treatment of AML. CLEC12A is expressed on 90-95% of AMLs, both on AML blast and their leukemic progenitors but not on normal early hematopoietic progenitors. MCLA-117 efficiently induced CLEC12A-mediated lysis of AML blasts (31-99%) in primary AML samples by autologous T cells, even at very low E:T ratios (E:T 1:3–1:97). Furthermore, MCLA-117 provoked robust T cell proliferation (7-226-fold). Based on its binding profile within the hematopoietic compartment, MCLA-117 is expected to specifically target blasts and leukemic stem cells while sparing the normal stem cells. A phase I clinical study is ongoing to evaluate the preliminary safety and efficacy of MCLA-117 in adult AML patients.

17:30-17:55

MARINE RAMAN

Senior Scientist, Protein Science, Immunocore

Investigating mechanisms of off target toxicity in an enhanced affinity TCR based immunotherapy

Monoclonal affinity-enhanced T cell receptors (TCRs) recognising tumour-associated antigens bring significant promise for cancer treatment. A key consideration in selecting appropriate targets is off target reactivity and extensive molecular and cellular testing is performed to safeguard against this. However, unpredicted off target effects still occur. TCR-engineered T cells recognising A1-MAGE-A3 led to cardiac arrest and death due to binding of an unrelated protein, Titin. Here, we investigate the structural basis of the cross-reactivity between A1-MAGE-A3 and A1-Titin. Using molecular structures of a soluble variant of the same MAGE-A3 TCR (termed MAG-IC3) in complex with either A1-MAGE-A3 or A1-Titin revealed molecular mimicry. Structurally-guided TCR mutations reduced cross-reactivity between MAG-IC3 and A1-Titin whilst maintaining TCR specificity towards A1-MAGE-A3.

17:55-18:20

ANGELA NEUBAUER

Head of Product Development, BIOMAY AG

PCFiT – a new approach to Immunotherapy using fusion proteins designed to induce a focused immune response

- General principle of Biomay´s PCFiT technology platform for induction of epitope-focussed immune responses
- Pre-clinical and clinical results obtained with BM32 – a recombinant vaccine for immunotherapy of grass pollen allergy
- PCFiT vaccines for other indications (e.g. infectious diseases

17:30-18:20

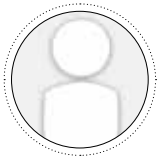
50 MINUTE EXECUTIVE PANEL DISCUSSION:

Overcoming Barriers to Global Biosimilar Adoption

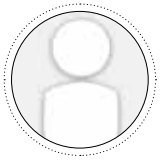
CHAIR: TBC

PANELLIST:
SANDEEP ATHALYE
Vice President and Head, CDMA, Biosimilars, Boehringer Ingelheim

PANELLIST:
GRAHAM FOXON
Managing Director, ReMAP Consulting



PANELLIST:
STEFAN ARNOLD
Managing Director, BPC Arnold GmbH
BioPharma Consulting



PANELLIST:
MATTHEW TURNER
Global Medical Director, Merck Group

Invitation to Senior Representatives x1

18:20-18:45

MIHRIBAN TUNA

Vice President Discovery, F-star

The use of bispecific antibodies to modulate anti-tumour immune

Combining immunotherapeutic antibodies for treatment of cancer patients has shown benefits over single agent treatment. An alternative to combining two antibodies is the development of bispecific antibodies that not only bring two biologies together but may result in novel mechanisms of action that are impossible to attain with combinations.

A murine-specific anti-LAG-3 and PD-L1 bispecific antibody was engineered which binds both antigens simultaneously and with nanomolar affinities. The anti-LAG-3/PD-L1 bispecific antibody inhibits LAG-3 binding to MHCII and PD-L1 binding to PD-1 and CD80, resulting in T cell activation in an in vitro assay. This potency translates into in vivo efficacy, where the anti-LAG-3/PD-L1 bispecific antibody decreased tumour burden in the MC38 colon carcinoma tumour model, both in early-established or well-established tumours. At the end of the study tumour-free animals were more numerous in the LAG-3/PD-L1 bispecific group than in the group given a combination of individual anti-LAG-3 and PD-L1 antibodies. The results were recapitulated in the CT26 murine colon cancer model, where the LAG-3/PD-L1 bispecific showed an increase of anti-tumour activity as compared to the combination of anti-LAG-3 and anti-PD-L1 antibodies. Thus, the preclinical data supports developing an anti-human LAG-3/PD-L1 bispecific for the treatment of cancer patients.

18:20-18:45

MARTIN SIEGEMUND

University of Stuttgart

Fusion proteins with hexavalent TRAIL assembly for cancer therapy

We developed single-chain formats of TNF-related apoptosis inducing ligand (scTRAIL) as components in tumor-associated antigen-targeted as well as non-targeted fusion proteins with hexavalent TRAIL assembly for cancer therapy, combining enhanced tumor specific activation of death receptors DR4 and DR5 with a good safety profile. Different protein arrangements were used to combine scTRAIL dimerization with for instance EGFR targeting. Using engineered scTRAIL molecules with improved thermal stability, we generated i.a. a new generation of EGFR-targeted diabody-scTRAIL fusion proteins characterized by an improved protein stability and composition and a high bioactivity in vitro as well as in mouse xenograft experiments.

18:20-18:45

PAUL CALVO

Director, Sterne, Kessler, Goldstein & Fox P.L.L.C.

18:45-19:45 Networking Drinks Reception

08:30-08:55 Refreshments

08:55-09:00 **Global Engage Opening Remarks**

09:00-09:35

KEYNOTE ADDRESS:
MARIE KOSCO-VILBOIS

Chief Scientific Officer, NovImmune SA

Foiling tumor microenvironments by unleashing phagocytes

- Phagocytes, of which the prototype is a macrophage but also encompasses dendritic cells and fibroblasts, play an important role in host homeostasis and defense
- Cancer cells have evolved mechanisms to suppress the anti-tumor role of phagocytes
- Targeting CD47, the ubiquitous 'don't eat me signal', reinstates healthy phagocyte function, as tumor killers and scavengers as well as in activation of anti-tumor T cells through antigen presentation
- Using bispecific antibodies to localize blocking CD47 to the tumor microenvironment, our therapeutic approach offers significant pharmacological and safety advantages to patients
- Launch of the first clinical program

09:35-10:10

KEYNOTE ADDRESS:
NICOLAS POIRIER

R&D Director, OSE Immunotherapeutics

Effi-DEM: a new generation checkpoint inhibitor which blocks pro-tumors and suppressor myeloid cells in the tumor microenvironment

The formation of an immunosuppressive tumor environment is regularly observed in cancer progression and involves several type of suppressor cells. Regulator T lymphocytes (Treg) exert a suppressor activity and the first generation of checkpoint inhibitors (CTLA-4, PD-1 and PDL-1).act on these regulator T cells. Beyond Tregs, Myeloid-Derived Suppressor Cells (MDSC) inhibits effector T lymphocyte functions. In parallel, Tumor Associated Macrophages (TAM) with suppressor and pro-tumoral functions accumulate locally and allow tumor growth and metastasis. A second generation of checkpoint inhibitors could therefore be developed, acting on these new suppressor myeloid cells. Effi-DEM is an antagonist monoclonal antibody of SIRP alpha, a novel immune checkpoint strongly expressed by myeloid suppressor cells. It restores effector functions of these suppressor cells. It demonstrated also preclinical efficacy in combination with other immunotherapies, in particular with checkpoint inhibitors acting on T lymphocytes.

09:00-10:10

ROUNDTABLES X4

During this time a series of four roundtables will offer attendees the opportunity to discuss important topics in the field of Biosimilars. The conversation will be facilitated by leaders in the respective fields and enable further exploration of themes raised in the conference agenda.

ROUNDTABLE 1:
The balance between optimising the price of your biosimilar and securing patient access

- What is the optimum list price for a biosimilar?
- How much of a discount is required to secure patient access at a local level?
- What are the payer evidence requirements to secure patient access at a national and local level?

GRAHAM FOXON
Managing Director,
ReMAP Consulting

TRACK CHAIR:
DAVID RABUKA

Global Head of R&D, Chemical Biology, Catalent Pharma Solutions

10:10-10:40

SOLUTION PROVIDER PRESENTATION:
ALEXANDER BAUMANN

Senior Director, Screening & Profiling Services Region Europe, DiscoverX

DiscoverX

10:10-10:40

SOLUTION PROVIDER PRESENTATION:

FUJIFILM Diosynth biotechnologies

10:40-11:40 Morning Refreshments / Poster Presentation Sessions / One to One Partnering Meetings

CANCER IMMUNOTHERAPY

11:40-12:05

JOACHIM KOCH
Project Leader, Affimed

12:05-12:45

EXECUTIVE PANEL DISCUSSION:
Advancing immunotherapy
This panel will examine themes and challenges in one of the most promising fields in modern medicine; focusing on the future of immunotherapy and the next steps forward.

CHAIR
VOLKER SCHELLENBERGER
President and CEO, Amunix

PANELLIST
JESSIE NI
Chief Scientific Officer, Irvine Scientific

Senior Representatives x2

12:45-13:15

SOLUTION PROVIDER PRESENTATION:
DAVID PEARLMAN
Director, Biologics Software Platform and Senior Scientist, Schrödinger GmbH
Computational Approaches in Antibody Design: Identifying and Reducing Liabilities early in the Discovery Process
Computational tools facilitating antibody optimization have improved greatly in recent years. These tools are finding increasing acceptance for liability assessment and reduction early in the discovery process. Using the BioLuminate software platform, we describe both how these calculations can be utilized for workflowed triage among multiple candidates, and how tools such as FEP can be used to suggest sequence engineering that can ameliorate identified liabilities (e.g. aggregation propensity) while maintaining affinity and stability.

SCHRÖDINGER.

ANTIBODY-DRUG CONJUGATES

11:40-12:05

RICHARD GREGORY
Chief Scientific Officer and Executive Vice President, ImmunoGen Inc
Optimizing the therapeutic Index of Antibody-Drug Conjugates
- Challenges of ADC Development
- Optimizing Linker/Payload Design
- A Look Towards the Future

12:05-12:45

EXECUTIVE PANEL DISCUSSION:
ADCs design and optimisation
Examining the design of ADC's and looking to the future of the field, this panel will draw together the knowledge of multiple leaders in ADC development.

CHAIR: TBC

PANELLIST
YUJI KASUYA
Senior Scientist, Kitasato Daiichi Sankyo Vaccine Co., Ltd, Japan

PANELLIST
PHILIPP HESS
Managing Director, Philipp Hess Associates

Senior Representatives x2

12:45-13:15

SOLUTION PROVIDER PRESENTATION:
JOHN GUNN
Ph.D., Senior Research Scientist, Chemical Computing Group
Modeling Protein-Protein Interactions with First-Principles Docking
Computer modeling of protein-protein interactions plays an increasingly important role in studies of biologics. This work presents a novel algorithm for predicting likely antigen epitopes from protein-protein docking results using the MOE software package. Protein structures are represented by a coarse-grained bead model which accurately reproduces the interaction energies of the corresponding all-atom model. An additional aggregation scoring term is provided by mapping hydrophobic patches derived from surface analysis onto the model structure. Automated sequence annotation is used to identify the antibody complementarity-determining regions to further constrain the docked poses. This approach generates good poses ranked in the top 100 in over 80% of the cases in the ZDOCK benchmark test set, a result superior to comparable published methods. Protein-protein residue contacts are then used to generate interaction fingerprints which serve to identify Boltzmann-weighted clusters of poses from which to extract consensus epitope residues. Using this method, at least one predicted epitope from the top-ranked five clusters has significant overlap with the native structure in over 50% of test cases.

CHEMICAL COMPUTING GROUP

13:15-14:15 Lunch / One to One Partnering Meetings

14:15-14:40

MARINA PAVLIDOU

Group Leader Selection Technologies, Pieris

Tumor-localized T cell costimulation with CD137-targeting bispecifics: From Flexible Design to In-Vivo Proof of Concept and Beyond

- Strong proof of concept and developability data for CD137/HER2 bispecific PRS-343
- Why immuno-stimulatory receptor targeting requires bispecifics for efficacy and safety
- How the versatile Anticalin-based multispecifics platform allows selecting the optimal bispecific geometry for a desired biological effect

14:40-15:05

SYD JOHNSON

VP Antibody Engineering, Macrogenics

From DART® to TRIDENT™: Therapeutic Applications of Bi- and Tri-specific Formats

- Salient properties of bivalent, trivalent and tetravalent DART and TRIDENT formats
- Tailoring avidity and valency for different target combinations and applications
- Examples in diverse therapeutic indications

15:05-15:30

YELENA BISHARYAN

Director of External Alliances, Tetragenetics

Antibodies Against Difficult to Express Membrane Protein Targets

Ion channels such as Kv1.3 have been historically difficult to raise antibodies against due to sequence conservation, paucity of cell surface epitopes, and poor expression levels in heterologous systems. Tetragenetics Inc. is addressing these issues by combining its unique technology for membrane protein expression in Tetrahymena thermophila, and antibody generation in phylogenetically diverse animals, to develop therapeutic antibodies against a range of ion channel targets including Kv1.3, a voltage-dependent channel produced by effector memory T-cells implicated in certain autoimmune disorders.

14:15-14:40

JENS WUERTHNER

Assistant Vice President, ADC Therapeutics

Avoiding a 2nd Tegenero incident: Learnings from a recent phase 1 biologics trial

- Introduction to domain antibodies
- Impact of autoantibodies on pharmacology
- Conducting a safe phase 1 trial with a molecule of unknown risk

14:40-15:05

JENS LOHRMANN

Senior Global Programme Manager, Novartis

Delivering consistent, stable ADCs presents drug developers with unique challenges. Besides technical hurdles, a key decisions is to "buy or make" these highly active compounds. Leveraging the know-how of CMOs can be very powerful, however to ensure an effective relationship, communication aspects are key and will be discussed. Technical challenges of site-transfers, especially with concomitant scale-up are to be expected. Case studies will be presented to discuss impact of conjugation process on key product quality attributes, as well as lessons learned from analytical transfers.

15:05-15:30

LUKE MASTERSON

Chemistry Group Leader, Spirogen

Antibody Pyrrolobenzodiazepine Conjugates

- Background and mode of action of Pyrrolobenzodiazepine anti-tumour agents
- Preclinical Development of Antibody Pyrrolobenzodiazepine Conjugates
- Update on clinical progress of Antibody Pyrrolobenzodiazepine Conjugates

15:30-16:00 Afternoon Refreshments / Poster Presentations

16:00-16:25

PETR OBRDLIK

Fellow, Novartis

Automated generic direct binding ELISA for potency measurements

Selection of an appropriate potency bioassay depends on the mode of action as well as other properties of the bio-therapeutic drug. If applicable, direct target-binding ELISA is often a preferred potency assay for pre-clinical and early clinical trials because of its low variability, easy execution and convenient lab infrastructure. Nevertheless, the establishment of such potency ELISA still requires target-specific development and drug-specific method qualification. To simplify the process, we first established a manual, generic direct binding ELISA method for measuring potency of process development samples as well as for quality control. In the meantime, this manual ELISA assay is successfully used for several drugs in pre-clinical and clinical trials. As the next step, the method protocol was adapted to allow for fully automated sample preparation, assay execution and potency measurement. In this presentation, we describe the critical protocol parameters and changes which had to be taken to achieve this goal.

16:25-16:50

ALEXANDER GOLOVANOV

Senior Lecturer (Associate Professor) and Principal Investigator, Manchester Institute of Biotechnology and School of Chemistry, University of Manchester, UK

Application of solution NMR spectroscopy for characterizing mAb formulations

Assessing how excipients affect self-association of monoclonal antibodies (mAbs) requires informative and direct in situ measurements which work for highly concentrated solutions. In our study we assessed a number of parameters which can be derived from solution NMR experiments and show that some of them can be used as a very sensitive measure for transient protein association in different formulations. Excipients, such as arginine glutamate, can have a significant effect on reducing transient interactions evident even for most soluble mAbs present at large concentrations. We discuss the application of NMR spectroscopy as an emerging tool providing useful complementary information for formulation development of mAbs and other therapeutic proteins.

16:50 Conference Close

POSTER PRESENTATIONS:

MAKING A POSTER PRESENTATION

Poster presentation sessions will take place in breaks and alongside the other breakout sessions of the conference. Your presentation will be displayed in a dedicated area, with the other accepted posters from industry and academic presenters.

We also issue a poster eBook to all attendees with your full abstract in and can share your poster as a PDF after the meeting if you desire (optional).

Whether looking for funding, employment opportunities or simply wanting to share your work with a like-minded and focused group, these are an excellent way to join the heart of this congress.

In order to present a poster at the forum you need to be registered as a delegate. Please note that there is limited space available and poster space is assigned on a first come first served basis (subject to checks and successful registration).

We charge an admin fee of €100 to industry delegates to present, that goes towards the shared cost of providing the poster presentation area and display boards, guides etc. This fee is waived for those representing academic institutions and not for profit organisations.

VENUE BERLIN, GERMANY:

The conference will take place in Berlin, Germany on the 6th-7th March 2017. The venue will be Leonardo Royal Hotel Berlin Alexanderplatz, Otto-Braun-Strasse 90, 10249 Berlin, Germany

Hotel accommodation will available at a group rate. You will be sent a direct link to the venue booking system after registering

DON'T DELAY, BOOK YOUR PLACE TODAY!

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To register your interest in the event, a member of our conference team will then be in touch within 24 hours to answer any questions and book your place for the event.

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Hotel accommodation will be available at a group rate.

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