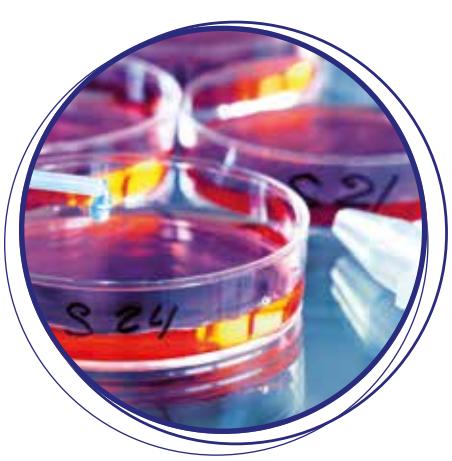
Global Engage

4TH BIOLOGICS & BIOSIMILARS CONGRESS: EUROPE

BERLIN, GERMANY

— 5-6 March 2018 —



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#GEBB18

Global Engage

Building on the success of our 2017 meeting, Global Engage is pleased to announce the **4th Biologics & Biosimilars Congress** which will be held on the 5th and 6th March, 2018 in Berlin, Germany. The conference will host over 60 expert speakers and panellists in three tracks across both days, and is expected to attract over 250 attendees and 30 poster presentations. The conference is part of Global Engage's successful Drug Discovery series which includes our Precision Medicine, Medicinal Chemistry and Synthetic Biology congresses.

Attracting industry, regulatory and academic experts working in all areas of antibody, protein and biosimilar research, the two-day meeting will explore a variety of topics across three tracks. With a strong focus on antibody based therapeutics, tracks 1 and 2 provide industry leaders with the opportunity to present updates on their strategy, pipeline and existing candidates in a variety of areas including antibody discovery and design, immuno-oncology, bispecific antibodies and antibody-drug conjugates. Other talks in these tracks will examine checkpoint inhibitor therapies and recent innovations in the exciting area of T-Cell therapeutics. Track 3 looks to cover developments in fusion proteins, novel scaffolds and immunogenicity considerations across protein biotherapeutics. The Biosimilars track 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.

This two-day interactive meeting will allow you the opportunity to keep up to date with cutting edge strategies, technologies and the latest research, as well as potential to keep abreast of your competitors through access to renowned solution providers, and to make lasting connections with other thought leaders, experts, businesses and entrepreneurs in your field.

EXPERT SPEAKERS Include:

RENE HOET
Head Antibody Lead Discovery & Optimization, Bayer

SEEMA KUMAR
Associate Director, Merck KGaA

ANDREAS PAHL
CSO, Heidelberg Pharma

JILL CARTON
Director, Biologics Discovery Janssen BioTherapeutics, Janssen R&D

DAY 1 – TRACK 1

Antibody Based Therapeutics: discovery and design

- Case study – multispecific antibodies
- Case study – treatments across the blood-brain barrier
- Case study – antibody discovery and optimization
- Panel Discussion – developing antibody therapeutics – strategies, techniques and challenges

DAY 1 – TRACK 2

Antibody-Drug Conjugates: design, stability optimization, linker and payload development

- Case study – amanitin based ADCs
- Case study – fragment antibody-drug conjugates
- Case study – novel carriers, linker and payloads

DAY 1 – TRACK 3

Biosimilars: design and optimization, commercialization strategies, quality control, IP and regulatory issues

- Case study – litigation studies
- Case study – global regulation trends
- Case study – patient-clinic relations
- Case study – bringing biosimilars to the commercial market
- Panel discussion – progress in the regulatory landscape for biosimilars

DAY 2 – TRACK 1

Immunotherapy

- Case study – bispecific t-cell engagers
- Case study – solid tumour immunotherapies
- Case study – checkpoint blockades
- Panel discussion - the impact of bispecific antibodies on oncology and challenges in developing novel cancer treating biologics

DAY 2 – TRACK 2

Antibody-Drug Conjugates: case studies

- Panel Discussion – Reviewing the progress of Antibody-Drug Conjugates and the next steps in ADC design

T-cell immuno-oncology

- Case study – conjugating cytokines for increasing tumor-targeting t-cell generation

DAY 2 – TRACK 3

Protein biotherapeutics: alternative scaffolds, fusion proteins, immunogenicity, protein expression

- Case study – alternative scaffolds
- Case study – fusion proteins
- Case study – immunogenicity

ROUNDTABLE SESSIONS

Session 1: Biological Therapeutics

- **Table 1:** Safety and efficacy of biologic therapeutics
- **Table 2:** Immunogenicity considerations
- **Table 3:** Antibody discovery techniques
- **Table 4:** New antibody therapeutics: bi- and multispecifics
- **Table 5:** Discovery and development of antibodies against benign inflammatory diseases
- **Table 6:** ADC optimisation

ROUNDTABLE SESSIONS

Session 2: Biosimilars

- **Table 1:** Patient access and pricing
- **Table 2:** Patient and public engagement
- **Table 3:** Overcoming barriers to biosimilar adoption
- **Table 4:** Strategies for addressing Intellectual Property barriers

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RENE HOET
Head Antibody Lead Discovery & Optimization, Bayer

ROLAND BUELOW
CEO, TeneoBio

ANDREAS PAHL
CSO, Heidelberg Pharma

JENS NIEWOEHNER
Group Leader, Roche

GOKHAN YAHIOGLU
Director of Chemistry, Co-founder, Antikor

SENIOR REPRESENTATIVE
Yumab

TANVIR TABISH
Head of Drug Product Development for Gene Therapy and Coagulation Factors, Shire

CATHERINE HUTCHINGS
Consultant, Heptares

TREVOR HALLAM
CSO, Sutro Biopharma

PHILIP HOWARD
Founder & CSO, Spirogen

MARTIN STEEGMAIER
Head Discovery & Site Head Large Molecule Research, Pharma Research & Early Development, Roche Innovation Center Munich

SEEMA KUMAR
Associate Director, Merck KGaA

JENNY THIRLWAY
Technical Director, Glythera

KARL ANDERSSON
CEO, Ridgeview

STEPHAN FISCHER
CEO, MAB Discovery

LISA MUELLER
Partner and Chair of the Life Science Group, Michael Best & Friedrich LLP

GRZEGORZ ORLIK
Head of Medical Affairs, Biosimilars and Generics Europe, Accord Healthcare

XAVIER FRAPAISE
Vice President Clinical Development, Merck Serono

CHRISTIAN MAASCH
Managing Consultant RA CMC/Biotech, Xendo Deutschland Gmbh

HITTO KAUFMANN
Global Vice President Biopharmaceuticals, Sanofi

VIBHA JAWA
Director Biologics and Vaccines, Merck Sharp & Dohme

AMRIK BASRAN
CSO, Avacta

TIMOTHY LOWINGER
CSO, Mersana

MATHIEU CINIER
CSO, Affilogic

SLAVOLJUB MILOSEVIC
Head of Technology Innovation, Medigene

BERND SCHLERETH
Senior Director, Non-clinical safety, Covagen

ROMAN IVANOV
Vice President, Research & Development, Biocad

OLIVER HILL
Vice President, APOGENIX AG

ARMIN SEPP
Associate Fellow, GSK

SYD JOHNSON
Vice President, MacroGenics

ANNICK DE VRIES
Head Diagnostics (Biologics), Sanquin Bloedvoorziening

BORIS GOROVITS
Senior Director, Pfizer

PAUL WASSMANN
Principal Scientist, Novartis

JOHAN NILVEBRANT
Researcher, KTH

NIGEL TEMPERTON
Senior Lecturer and Joint Head, Viral Pseudotype Unit, University of Kent

ANGUS DALGLEISH
Professor of Oncology, St George's University of London

CONFIRMED SPEAKERS

BARBARA VALSASINA
Project and Group Leader,
Nerviano Medical Sciences

JILL CARTON
Director, Biologics Discovery
Janssen BioTherapeutics,
Janssen R&D

ANDREW WILLIAMS
Partner, McDonnell Boehnen
Hulbert & Berghoff LLP

CLAIRE DOBSON
Associate Director Antibody
Discovery and Protein
Engineering, MedImmune

JENS LOHRMANN
Senior Global Program
Manager, Novartis

ADAM CLAUSS
Scientist, LEO Pharma

WILL GOUNDRY
Associate Principal Scientist,
AstraZeneca

08:00-08:55 Registration & Refreshments

08:55-09:00 **Global Engage Welcome Address and Morning Chair's Opening Remarks**

09:00-09:35

KEYNOTE ADDRESS:
RENE HOET
Head Antibody Lead Discovery & Optimization, Bayer
New techniques for discovering therapeutic antibodies – Title TBC

BIOLOGICS

09:35-10:10

KEYNOTE ADDRESS:
Invitation Out
Title TBC

BIOSIMILARS

09:35-10:10

KEYNOTE ADDRESS:
ISABELL REMUS (Reserved)
Head Biopharmaceuticals Western Europe, Sandoz
The commercial landscape of the biosimilar industry – Title TBC

ANTIBODY-BASED THERAPEUTICS

10:10-10:40

SOLUTION PROVIDER PRESENTATION:
SENIOR REPRESENTATIVE
Schrödinger GmbH
Title TBC

ANTIBODY-DRUG CONJUGATES

10:10-10:40

SOLUTION PROVIDER PRESENTATION

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BIOSIMILARS

10:10-10:40

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10:40-11:50 Morning Refreshments / Poster Presentations / One-to-One Partnering Meetings

Track Chair: JOHAN NILVEBRANT, Researcher, KTH

11:50-12:15

ROLAND BUELOW
CEO, TeneoBio
Multi-specific antibodies for human therapy

TeneoBio, Inc. is developing a new class of therapeutics, Human Heavy Chain Antibodies (UniAbs™). The high affinity and robust function of UniAbs combine antibody specificity with excellent developability. The UniAbs' fully human VH domains, UniDabs™, are versatile building blocks for the development of therapeutics with multi-specificity. TeneoBio's antibody discovery engine is based on UniRat™, a proprietary human heavy chain only, transgenic rat. For antibody discovery we apply a novel sequence-based discovery approach using NGS, bioinformatics and high-throughput recombinant protein expression. We developed multivalent antibodies with superior tumor cell cytotoxicity and specificity including UniAbs targeting CD38 and PDL1and T-cell engaging antibodies targeting BCMA on plasma cells. Our results demonstrate that UniDabs are versatile building blocks for the generation of multi-valent therapeutics with superior potency and specificity.

Track Chair:

11:50-12:15

ANDREAS PAHL
CSO, Heidelberg Pharma
HDP-101 of "ATAC" Platform: Proprietary, Amanitin-based ADC

Applies New Mechanism for Impacting Multiple Myeloma

- Heidelberg Pharma: First company developing RNA Polymerase II inhibitors for cancer treatment
- Amanitin is the most effective and specific inhibitor of RNA Polymerase II
- ATAC: ADC technology harnessed to deliver this new mode of action to cancer patients
- ATACs kill both dividing and dormant tumor cells
- ATACs are effective on low expressed targets
- ATACs have a large therapeutic index and favorable tolerability, no liver toxicity
- Deletion of p53 is a payload-specific predictive biomarker for ATACs
- BCMA is an ideal target due to its restricted expression on malignant Multiple Myeloma cells
- ATAC/HDP-101: ideal approach to target low expressed BCMA on slowly proliferating tumor cells
- HDP-101: High efficacy in animal models; long-lasting remission after single treatment
- First-in-Man starts end of 2018

Track Chair:

11:50-12:15

LISA MUELLER
Partner and Chair of the Life Science Group, Michael Best & Friedrich LLP
Global Legal Issues Associated with Biosimilars

This presentation will focus on:

- The current state of biosimilars globally including the number of biosimilars currently on market in the major biosimilar "player" countries;
- Regulatory issues and challenges faced by biosimilars globally (e.g., comparability studies, Phase III studies, interchangeability, naming requirements, etc.); and
- Patent challenges faced by biosimilar companies including conducting a freedom-to-operate analysis in various jurisdictions to identify the relevant patents (if any) at issue, ways to minimize risk and high level review of patent litigation involving biosimilars worldwide.

12:15-12:40

JENS NIEWOEHNER

Group Leader, Roche

Effector functions of Brain Shuttle antibody therapeutics

- Transport of therapeutic antibodies into the brain using Brain Shuttle technology
- Safety aspects of Brain Shuttle molecules with Fc effector function
- Choosing the right format for safety and efficacy

12:15-12:40

GOKHAN YAHIOGLU

Director of Chemistry, Co-founder, Antikor

Not too big-not too small: Fragment Drug Conjugates (FDCs) as alternatives to ADCs for solid tumours

Antikor is developing a proprietary platform to discover and develop FDCs for solid tumours. ADCs have failed to deliver on their early promise with over 20 clinical development trials discontinued. It is clear that one size does not fit all indications and addressing difficult solid tumours requires an alternative approach. Using smaller antibody formats is an attractive option due to their faster elimination from the circulation and enhanced tumour penetration. Antikor's OptiLink technology where payload loading is optimised to obtain high drug-to-antibody ratio FDCs, allows the early delivery of a bigger cytotoxic 'hit.' Compelling data with our scFv antibody format FDCs show:

- Optimal PK/PD properties
- Superior in vivo efficacy in Her2 models for breast and gastric cancer compared to the ADC
- Rapid tumour penetration and clearance
- Better tolerability and are less toxic than the ADC equivalent

We believe this fast-in-fast-out approach will result in low systemic exposure and an improved TI.

12:15-12:40

GRZEGORZ ORLIK

Head of Medical Affairs, Biosimilars and Generics Europe, Accord Healthcare

Challenges in medical communication for biosimilar products

Communication about biosimilar products changes. Some issues become less critical, but we have other emerging. Typical points cover:

- Similarity vs. identity to reference product
- Substitution and interchangeability
- Safety (with special focus on autoimmunity)
- Communication of pricing policy and access to the treatment

12:40-13:10

SOLUTION PROVIDER PRESENTATION: SENIOR REPRESENTATIVE

Yumab

Title TBC

12:40-13:10

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12:40-13:10

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13:10-14:10 Lunch / One-to-One Partnering Meetings

Track Chair: NIGEL TEMPERTON, Senior Lecturer and Joint Head, Viral Pseudotype Unit, University of Kent

Track Chair:

Track Chair:

14:10-15:00

PANEL DISCUSSION:

Developing Antibody based therapeutics – strategies, techniques and challenges

TANVIR TABISH

Head of Drug Product Development for Gene Therapy and Coagulation Factors, Shire

CATHERINE HUTCHINGS

Consultant, Heptares

Invitation Sent to Senior Representatives x2

14:10-14:35

TREVOR HALLAM

CSO, Sutro Biopharma

Novel antibodies for ADC usage – Title TBC

14:10-14:35

XAVIER FRAPAISE

Vice President Clinical Development, Merck Serono

The end of clinical trials in patients?

14:35-15:00

PHILIP HOWARD

Founder & CSO, Spirogen

Development and optimisation of novel payloads – Title TBC

14:35-15:00

ANNICK DE VRIES

Head Diagnostics (Biologics), Sanquin Bloedvoorziening

Serum level measurements for biologics/ biosimilars: real life data

- Experience from routine diagnostics on PK and ADA measurements
- One dos/multitude of serum levels; impact of immunogenicity on PK
- Validation of PK/ADA setup for originators for biosimilars

15:00-15:25

JILL CARTON
Director, Biologics Discovery Janssen BioTherapeutics, Janssen R&D

Advancing antibody discovery for efficient antibody therapeutics development

While the biologics market is expanding rapidly with novel and effective therapeutics, the challenges in discovery are steadily increasing. Discovery must be more nimble, efficient, and seamless with development. This requires a well-designed discovery process, access to excellent and diverse molecule sources, and earlier alignment with the development organization. Several cases studies will demonstrate our lessons learned and adaptions.

15:00-15:25

SEEMA KUMAR
Associate Director, Merck KGaA

ADC Bioanalytical Strategies: PK Assay Continuity Between Discovery and Development

Depending on the PK question that needs to be answered, the strategies and bioanalytical approaches employed for ADC assay development may need to be adapted. At the discovery stage, due to the limited availability of critical reagents, time and resources, flexible "fit-for-purpose" assays are often employed. On the contrary, the late stage non-clinical drug development typically requires qualified and validated assays. The differences in critical reagents and assay formats/platforms adopted at different stages of drug development may impact the observed analyte concentration and the associated PK profile/parameters. However by applying rational scientific understanding of what each assay format and assay reagent is measuring, an appropriate interpretation of observed data can be made. Case studies on assay continuity during various stages of non-clinical development of ADC (Discovery to Development) will be presented.

15:00-15:25

ANDREW WILLIAMS
Partner, McDonnell Boehnen Hulbert & Berghoff LLP

Strategies in IP and Biosimilars – Title TBC

15:25-15:55

SOLUTION PROVIDER PRESENTATION: KARL ANDERSSON
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

15:25-15:55

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15:25-15:55

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15:55-16:45 Afternoon Refreshments / One-to-One Partnering Meetings

16:45-17:10

MARTIN ORECCHIA
(Reserved)
Project Leader, Antibody Engineering, GSK
Use of phage and yeast displays in antibody production – Title TBC

16:45-17:10

JENNY THIRLWAY
Technical Director, Glythera
Assessing the therapeutic efficacy of novel toxins conjugated using the stable PermaLink© technology
Antibody Drug Conjugates (ADCs) are an emerging class of targeted therapeutics with the potential to improve therapeutic index over traditional chemotherapy. By combining the targeting power of antibodies with the cell killing capability of potent cytotoxic molecules, it is possible to kill cancer cells more effectively whilst reducing debilitating side effects. Glythera's PermaLink® technology has been validated in a range of ADC models and demonstrated improved stability, efficacy and tolerability profiles. Using these important differentiators Glythera has accessed a portfolio of toxins with known and novel modes of action and has completed the three part ADC jigsaw by additionally accessing novel antibodies through its partners.

16:45-17:10

BIOSIMILARS INDUSTRY PRESENTATION

17:10-17:40

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17:10-17:40

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17:10-17:40

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17:40-18:05

STEPHAN FISCHER
CEO, MAB Discovery
The optimal access to functional diversity of antibodies: Single B-cell cloning from Wild-Type rabbits
MAB Discovery successfully applies a unique technical and conceptual approach to functional diversity of antibodies based on B-cell cloning from immunized wild-type rabbits. One obtains a large number of potent antibodies with very diverse paratopes (binding domains), while keeping the modality, a classical monoclonal antibody, constant. The emerging picture is surprising. The results of presented examples show that functional diversity of antibodies with different paratopes has been very much underestimated. The produced antibody products add significant potential to novel therapies, in particular with validated targets. This outcome is achieved without additional technical and target related risks and provides a very promising alternative to antibody engineering.

17:40-18:05

BARBARA VALSASINA
Project and Group Leader, Nerviano Medical Sciences
Developing an ADC payload platform – Title TBC

17:40-18:30

PANEL DISCUSSION:
Progress in the regulatory landscape for biosimilars

CHRISTIAN MAASCH
Managing Consultant
RA CMC/Biotech, Xendo Deutschland Gmbh

Invitation Sent to Senior Representatives x3

18:05-18:30

CLAIRE DOBSON
Associate Director
Antibody Discovery and Protein Engineering, MedImmune
Antibody engineering – Title TBC

18:05-18:30

WILL GOUNDRY
Associate Principal Scientist, AstraZeneca
Challenges and Opportunities in the Synthesis of ADC Payloads

- An overview of ADC payloads currently in development
- A detailed discussion of AstraZeneca's payloads
- What challenges should you consider when scaling up the synthesis of an ADC payload?
- A case study for the scale-up of AstraZeneca's Tubulysin payload
- Future perspective: what are the opportunities for new payloads

17:40-18:30

Continued

18:30	Chair's Closing Remarks / End of Day One
18:30-19:30	Networking Drinks Reception

08:30-09:00 Refreshments

BIOLOGICS

09:00-09:35

KEYNOTE ADDRESS:
HITTO KAUFMANN
Global Vice President Biopharmaceuticals, Sanofi

Developing Next Generation Biologics

- Adapting to the evolution of diverse biologics pipelines
- Innovation as a key driver to deliver superior medicines to patients
- Convergence of technologies

09:35-10:10

KEYNOTE ADDRESS:
Invitation Out

BIOSIMILARS

09:00-10:10

ROUNDTABLE DISCUSSIONS:
Table 1: Patient access and pricing

Table 2: Patient and public engagement

Table 3: Overcoming barriers to biosimilar adoption

Table 4: Strategies for addressing Intellectual Property barriers

IMMUNOTHERAPY

10:10-10:40

SOLUTION PROVIDER PRESENTATION:
SENIOR REPRESENTATIVE
DNAlytics

Title TBC

ANTIBODY DRUG CONJUGATES

10:10-10:40

SOLUTION PROVIDER PRESENTATION

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PROTEIN BIOTHERAPEUTICS

10:10-10:40

SOLUTION PROVIDER PRESENTATION:
SENIOR REPRESENTATIVE
Chemical Computing Group

Title TBC

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

Track Chair: ANGUS DALGLEISH, Professor of Oncology, St George's University of London

11:40-12:05

MARTIN STEEGMAIER
Head Discovery & Site Head Large Molecule Research, Pharma Research & Early Development, Roche Innovation Center Munich

Pioneering antibody technology – Advancing transformative cancer immunotherapy agents

- Therapeutic efforts to engage the immune system against cancer has generated exciting breakthroughs and clinicaly meaningful benefit to a subset of patients. New bi- and multi-specific antibodies are now in various phases of clinical development and will become the next generation of antibody-based therapies.
- We have generated a portfolio of T cell bispecific antibodies and novel, engineered targeted immune-modulators that show promising pre-clinical and clinical activity as single agent or in combination with other cancer immunotherapy agents.
- The CrossMAb technology has proven to be very versatile, allowing the generation of various bispecific antibody formats providing great opportunity to tackle novel biology and to convey superior efficacy.
- Examples will be given how antibody format fundamentally influences the mode of action and activity of these novel immunotherapy agents.

Track Chair:

11:40-12:05

TIMOTHY LOWINGER
CSO, Mersana

Pre-clinic to clinical trial case study – Title TBC

Track Chair:

11:40-12:05

VIBHA JAWA
Director Biologics and Vaccines, Merck Sharp & Dohme

Developing novel proteins for immunology treatments

12:05-12:55

PANEL DISCUSSION:

The impact of bispecific antibodies on oncology and challenges in developing novel cancer treating biologics

ROLAND BUELOW
CEO, TeneoBio

Invitation Sent to Senior Representatives x3

12:55-13:25

SOLUTION PROVIDER PRESENTATION

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12:05-12:55

PANEL DISCUSSION:

Reviewing the progress of Antibody-Drug Conjugates and the next steps in ADC design

Invitation Sent to Senior Representatives x4

12:55-13:25

SOLUTION PROVIDER PRESENTATION

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12:05-12:30

AMRIK BASRAN
CSO, Avacta
Novel scaffold protein developments and applications – Title TBC

12:30-12:55

MATHIEU CINIER
CSO, Affilogic
The use of the Nanofitin alternative scaffold as a versatile platform for radioimaging and drug conjugate: a case study with anti-EGFR Nanofitins cross-reacting on both the human and murine EGFR

Key advantages of the Nanofitin technology as a vector for radioimaging

- Possibility to tailor the selection to obtain cross-reactive Nanofitin
  - ▷ Better significance of the preclinical studies in murine model in term of biodistribution
- Fast systemic clearance
  - ▷ Compatible with fast decaying radio-isotope
  - ▷ Simple radioactive waste handling
  - ▷ Better patient compliance
  - ▷ Higher production capacity
- No cysteine – regioselective conjugation allowed
- High stability – ease of chemical conjugation
- No accumulation in healthy organ
- High tumor to blood ratio at short time frame

Key advantages of the Nanofitin technology as a vector for drug conjugate

- Small scaffold – high tissue penetration
- Fast clearance can be tuned to allow longer resilience via proprietary half life extension technology
- Examples will be given of the versatlity of the scaffold
  - ▷ Can be easily conjugated to payload via chemical conjugation or genetic fusion (immunotoxin, immuno enzyme)
  - ▷ Can be conjugated to Nanoparticle

12:55-13:25

SOLUTION PROVIDER PRESENTATION:

SENIOR REPRESENTATIVE
KBI Biopharma
Title TBC

13:25-14:20 Lunch / One-to-One Partnering Meetings

14:20-14:50

SLAVOLJUB MILOSEVIC
Head of Technology Innovation, Medigene
Combining innovative bioinformatics, cellular tools and robotics to advance adoptive T cell therapies

14:50-15:15

BERND SCHLERETH
Senior Director, Non-clinical safety, Covagen
Immunogenicity of bispecific antibody constructs and what about the targets?

- Immunogenicity of novel biotherapeutics is a major hurdle in drug development
- Here, we report on the immunogenicity of a novel bispecific antibody construct (TNFa/IL-17 dual cytokine inhibitor) for the treatment of inflammatory diseases
- Interestingly, our data indicate that the immunogenicity is a consequence of dual target engagement and target structure rather than the intrinsic characteristics of the bispecific antibody construct

14:20-15:15

ROUNDTABLE DISCUSSIONS:

Table 1: Safety and efficacy of biologic therapeutics

Table 2: Immunogenicity considerations

Table 3: Antibody discovery techniques
STEPHAN FISCHER
CEO, MAB Discovery

Table 4: New antibody therapeutics: bi- and multispecifics
ROMAN IVANOV
Vice President, Research & Development, Biocad

Table 5: Discovery and development of antibodies against benign inflammatory diseases
ADAM CLAUSS
Scientist, LEO Pharma

Table 6: ADC optimisation
JENS LOHRMANN
Senior Global Program Manager, Novartis

14:20-14:50

OLIVER HILL
Vice President, APOGENIX AG
Development of fusion proteins

14:50-15:15

ARMIN SEPP
Associate Fellow, GSK
A PET imaging study of the tissue distribution and elimination kinetics of an 89Zr-labelled albumin-binding domain antibody (AlbudAb) in healthy volunteers

We have studied the tissue distribution and elimination kinetics of 89Zr-labelled albumin-binding domain antibody (AlbudAb) in healthy human volunteers. Extended plasma half-life was observed and combined with PET imaging data which indicated rapid initial tracer distribution in the vasculature followed by gradual tissue-dependent penetration which will be analyzed by physiologically-based pharmacokinetic (PBPK) modeling. Albumin-like plasma PK suggests that AlbudAbs can be useful for increasing and modulating the exposure of therapeutic payloads attached to the molecule.

IMMUNOTHERAPY

15:15-15:40

SYD JOHNSON
Vice President, MacroGenics
Bispecific approaches for immuno-oncology – Title TBC

T-CELL IMMUNO-ONCOLOGY

15:15-15:40

DEBORAH CHARYCH (Reserved)
Executive Director, Nektar Therapeutics
Conjugated cytokines for activating IL2 pathways to increase tumor targeting t-cells – Title TBC

PROTEIN BIOTHERAPEUTICS

15:15-15:40

BORIS GOROVITS
Senior Director, Pfizer
Immunogenicity studies and evaluation strategies for new biological entities

15:40-16:10 Afternoon Refreshments / One-to-One Partnering Meetings

16:10-16:35

CAROLINE BAUMER-KLESTIL (Reserved)
Apeiron Biologics, Medical Affairs Manager
Checkpoint blockade approaches for immuno-oncology – Title TBC

16:10-16:35

LAURENT POIROT (Reserved)
Head of Early Discovery, Cellectis
Engineering next generation CAR-T cells

16:10-16:35

PAUL WASSMANN
Principal Scientist, Novartis
An analytical tool-box enabling efficient lead candidate selection during Developability Assessment of Therapeutic Proteins

Early lead selection of biotherapeutics during preclinical development requires careful characterization of a variety of molecule properties to reduce the risk to encounter unexpected obstacles during technical development. Unlike monoclonal antibodies with defined strategies addressing common liabilities, therapeutic proteins pose next level challenges setting-up a strategy for identification of candidates with best developability characteristics. To support a target profile based characterization during developability assessment of therapeutic proteins, an analytical tool-box concept is used at Novartis. The concept will be presented and supported by selected case studies.

16:35-17:00 No Presentation in this Track

16:35-17:00 **T-cell Industry Presentation**

16:35-17:00 **CHRISTIAN MAASCH**
Managing Consultant RA CMC/Biotech, Xendo Deutschland Gmbh
Biophysical methods to take center stage in orthogonal analytics for comparability exercises and quality tasks of biologics

17:00 Conference Close

POSTER PRESENTATIONS

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