4TH ANNUAL

PEGS CHINA

Protein & Antibody Engineering Summit

第四届中国蛋白与抗体工程及研发峰会

March 28-30, 2017 | Shanghai, China

GRAND HYATT SHANGHAI, PUDONG

Register by January 6

SAVE UP TO $500

KEYNOTE SPEAKERS

Mitchell Ho, Ph.D.
Senior Investigator, Laboratory of Molecular Biology, National Cancer Institute, National Institutes of Health

Bertil Lindmark, M.D., Ph.D.
CMO, ASLAN Pharmaceuticals

Lei Zheng, Ph.D.
Associate Professor, Oncology and Surgery, Gastrointestinal Cancer Program, Tumor Immunology Program, Johns Hopkins University

Xiangyang Zhu, Ph.D.
CEO, Huabo Biopharma (Shanghai) Co., Ltd.

2017 CONFERENCE PROGRAMS

MARCH 28-29

- Protein & Antibody Engineering
  蛋白质与抗体工程
- Protein Aggregation & Stability
  蛋白质聚集和稳定性

MARCH 29-30

- Immuno-Oncology
  肿瘤免疫疗法
- Analytical Characterization of Biotherapeutics
  生物药物特性分析

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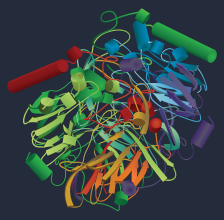

CAMBRIDGE HEALTHTECH INSTITUTE'S 4TH ANNUAL

PEGS CHINA

Protein & Antibody Engineering Summit

第四届中国
蛋白与抗体工程及研发峰会

March 28-30, 2017 | Shanghai, China

GRAND HYATT SHANGHAI, PUDONG

Join your peers and leading players in the worldwide biopharmaceutical industry to develop and foster collaboration among international and domestic China companies and institutions.

As China rises to join the ranks of global biopharmaceutical powerhouse, the true test lies not only in their regulatory guidance and pathways, but also in their successful research and development of novel biotherapeutics. Industry leaders and visionaries will convene at the Fourth Annual **PEGS Summit** in **Shanghai, China** on **March 28-30, 2017** to share innovative discovery programs, advancements in cutting-edge technology, best practices and experiences in problem solving.

NEW FOR 2017 With the growing importance and significance of immunotherapy as a potential game-changer in the fight against cancer, we have added a track on "Immuno-Oncology" which will showcase the pipelines and progress of immunotherapy programs of Chinese and international companies.

3 Days | 4 Conferences | 200+ Global Participants

60+ Presentations from Industry Experts Featuring Case Studies and Unpublished Data

MARCH 28-29

TRACK 1:

Protein & Antibody Engineering
蛋白质与抗体工程

The Protein & Antibody Engineering track at PEGS China invites academic researchers and industry practitioners to share their passion in the design, discovery and engineering of protein and antibody molecules, and discuss the innovative strategies used to overcome the challenges along the way.

TRACK 2:

Protein Aggregation & Stability
蛋白质聚集和稳定性

Aggregates and particles pose challenges in protein stability and solubility, causing immunogenicity concerns and affecting the formulation strategies. This track will examine aggregation formation and challenges to solubility and protein formulation.

MARCH 29-30

TRACK 3:

Immuno-Oncology
肿瘤免疫疗法

At CHI's Inaugural Immuno-Oncology track at PEGS China, we are looking to engage thought leaders and fore-runners in the field to review the current progress in China's immuno-oncology field, and highlight innovative approaches and cutting-edge technologies in advancing these molecules into the clinic.

TRACK 4:

Analytical Characterization of Biotherapeutics
生物药物特性分析

As China takes on novel and more complex biotherapeutics, one of the biggest challenges is the ability to quickly and accurately characterize these new molecules. This track will explore strategies to optimize molecules during early stage development, as well as approaches in structure-function elucidation for these novel and biosimilar products.

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KEYNOTE SPEAKERS

Engineering Single-Domain Antibodies for Cancer Therapy

Mitchell Ho, Ph.D., Senior Investigator, Laboratory of Molecular Biology, National Cancer Institute, National Institutes of Health

Antibody Drug Developments: Biosimilar vs Innovation – Finding a Way to Meet the Needs in China

Xiangyang Zhu, Ph.D., CEO, Huabo Biopharma (Shanghai) Co., Ltd.

Multimodal Cancer Therapy - Dynamic Process-Based Immuno-Oncology

Bertil Lindmark, M.D., Ph.D.
CMO, ASLAN Pharmaceutical

Rational Combination of Immune-Oncology Agents

Lei Zheng, Ph.D., Associate Professor, Oncology and Surgery, Gastrointestinal Cancer Program, Tumor Immunology Program, Johns Hopkins University

RESEARCH POSTER SUBMISSION

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by February 10, 2017.

Reasons you should present your research poster at this conference:

- Your poster will be showcased to our international delegation
- Receive US$50/¥200 off your registration
- Your poster title will be published in our conference materials
- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes

DEADLINE FOR POSTER SUBMISSION: FEBRUARY 10, 2017

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Discount applies to attendees from the same organization registering for the same event. All registrations must be submitted together to qualify for the discount.

ALUMNI DISCOUNT - SAVE 20%
CHI appreciates your participation at our events. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

JOIN THE PEGS COMMUNITY ONLINE

TRACK 1:
Protein & Antibody Engineering
蛋白质与抗体工程

TRACK 2:
Protein Aggregation & Stability
蛋白质聚集和稳定性

7:30 am Registration and Morning Coffee

PLENARY KEYNOTE SESSION

8:50 Chairperson's Opening Remarks
Zhenping Zhu, Ph.D., Executive Vice President, Global Biologics R&D, Kadmon Corp, LLC

9:00 Engineering Single-Domain Antibodies for Cancer Therapy
Mitchell Ho, Ph.D., Senior Investigator, Laboratory of Molecular Biology, National Cancer Institute, National Institutes of Health
Antibodies have a major role in cancer treatment. For increased efficacy, antibodies can be designed to inhibit signaling pathways responsible for cancer development. By decreasing antibody size, cryptic or buried functional regions in receptors can be targeted. There is also a need to identify new therapeutic targets in cancer.

9:30 Antibody Drug Developments: Biosimilar vs Innovation – Finding a Way to Meet the Needs in China
Xiangyang Zhu, Ph.D., CEO, Huabo Biopharma (Shanghai) Co., Ltd.
A landscape for antibody development in China will be discussed, especially on the pros and cons between biosimilar and innovative drugs. This presentation will also explore strategies to meet China's medical needs; and discus how companies can generate profits given the competitive drug development landscape.

10:00 Coffee Break

10:35 Chairperson's Remarks
Zhenping Zhu, Ph.D., Executive Vice President, Global Biologics R&D, Kadmon Corp, LLC

DISPLAY LIBRARIES AND ANTIBODY GENERATION

10:40 Recombinant Antibody Display Libraries – Design, Construction and Selection
Eunice Zhou, Ph.D., Associate Adjunct Professor, Anesthesia, UC San Francisco
An efficient approach to generate monoclonal antibodies is the recombinant antibody display library coupled with various selections. In this study, we will discuss the specifications of different recombinant Ab display libraries including naïve, synthetic, and nature-inspired libraries with regard to the Ab diversity and stability, as well as the factors that impact on the performance of different Ab display libraries. We will also describe a number of selection strategies to difficult targets, such as membrane proteins.

11:10 Generation of Humanized Antibody Transgenic Animal (CAMouse) for Producing Human Antibody
Liangpeng Ge, Ph.D., Director, Institute of Bingengineering, Chongqing Academy of Animal Sciences
Humanized antibody transgenic animals (CAMouse) are cultivated by Chongqing Academy of Animal Sciences, which is characterized by different temporal and spatial human/mouse immunoglobulin gene expression patterns during development, with normally developing B-cell, high antibody expressing level and abundant rearrangement diversity, it can be used to directly produce human immunoglobulin (Ig G) for clinic.

11:40 A Novel Platform for Human Antibody Discovery Using Yeast Display Antibody Library
Aichi Zhao, Ph.D., President, R&D, OriMabs, Ltd.
Yeast display is an attractive strategy for antibody discovery attributed to its eukaryotic system and the capability of FACS utilization for efficient high-affinity antibody sorting. However, the low transformation efficiency of yeast greatly impedes the wide use of yeast display in antibody discovery. We have made breakthrough progress by improving the yeast transformation efficiency 1000 times higher than traditional method, which enable us to construct very large library efficiently. Using the optimized protocols, we have constructed a large antibody library containing 110 billion repertoires and isolated around 100 novel antibodies for many tumor markers.

10:35 Chairperson's Remarks
Joy Zhou, Ph.D., Principal Scientist/Associate Director, DP MST, Shire

CHALLENGES IN PROTEIN STABILITY

10:40 Oxidative Post-Translational Modification - Impact on Stability and Formulation of Protein Therapeutics
Christian Schoeneich, Ph.D., Takeru Higuchi Distinguished Professor and Chair, Pharmaceutical Chemistry, University of Kansas
Antibodies are target for a large variety of chemical degradation reactions during processing and storage. This presentation will provide new examples, where forced and long-term degradation studies have led to the characterization of novel degradation products. Experimental evidence for the effect of glycoform diversity and antibody-drug conjugation on the chemical degradation of antibodies will be presented.

11:10 Heavy Chain of Mouse IgM Can Be Cleaved between CH1 and CH2 Domains by a Protease Present in Serum
Tomasz Klaus, MSc., Research Assistant, Malopolska Centre of Biotechnology, Jagiellonian University in Krakow
During research on IgM stability we discovered that N-terminal part of a mouse IgM heavy chain can be cleaved off by a factor present in serum. We identified the sequence prone to fragmentation and developed mutated molecules which are resistant to N-terminus trimming. Importantly, we observed that IgM fragmentation occurs in blood typing reagents and it reduces their shelf life. Thus, the mutated IgMs may become novel highly stable diagnostic reagents.

11:40 Impact of Product Heterogeneity on Product Biological Activity and Stability in the Context of Bio-Therapeutics
Ravish Patel, Ph.D., Scientist, Bioanalytical (Biologics), Analytical Development Lab, EPR Centre for Cancer Research and Bioinformatics Pvt. Ltd. (A Vitane Group of Companies)
Biosimilar product should be "highly similar" to prior approved reference product (RLD) and will have "no clinically meaningful differences" in their safety or efficacy. Due to relative complexities in producing biosimilar product small differences in the design and execution of manufacturing process can have a large influence of product related-, process related-,or host related impurities protein profile of a finished product, which may trigger immunogenicity and change the clinical profile requiring elaborate animal studies and human clinical studies.

TRACK 1:
Protein & Antibody Engineering
蛋白质与抗体工程

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing

2:00 Chairperson's Remarks
Mitchell Ho, Ph.D., Senior Investigator, Laboratory of Molecular Biology, National Cancer Institute, National Institutes of Health

ENGINEERING OF PROTEINS AND TARGETS

2:05 T-E Pharmaceuticals: A Modular Platform to Combine Targeting (T) and Effector (E) Functions with Precision
Tse-wen Chang, Ph.D., President & CEO, Immunwork, Inc.
For improving efficacy and safety profiles of various biologics, Immunwork develops a T-E technology platform to generate novel therapeutic molecules (including ADCs, bispecific Abs, and other multi-functional biologics) containing both targeting and effector moieties. The moieties are prepared separately based on multi-arm linker units and joined by click chemistry. The modular design feature of T-E platform allows the development of versatile T-E drugs for potential applications in oncology and beyond.

2:35 Computationally-Driven Engineering of an Anti-Tumor Antibody
Chris Bailey-Kellogg, Ph.D., Professor, Computer Science, University of Dartmouth
In order to enable development of CAR-T therapies targeting the tumor ligand B7H6, we implemented integrated computational-experimental methods to engineer a better humanized variant of a murine antibody, and to determine the epitope that it targets on the ligand. Our humanization method maintained near wild-type binding affinity, even though a traditional CDR grafted variant failed even to express. Our epitope mapping method optimized a small set of mutagenesis experiments that successfully revealed hotspot residues key to recognition. The success of our methods for these and other antibodies demonstrate the impact computational protein design can have throughout the pipeline of biotherapeutic discovery and engineering.

3:05 Structural Hot Spots for the Solubility of Globular Proteins
Joost Schymkowitz, Ph.D., Professor and Principal Investigator, Cellular and Molecular Medicine, VIB Switch Lab/University of Leuven
We here show an anti-correlation between the number of aggregation prone regions (APRs) in a protein sequence and its solubility, suggesting that mutational suppression of APRs provides a simple strategy to increase protein solubility. We show that mutations at specific positions within a protein structure can act as APR suppressors without affecting protein stability. These hot spots for protein solubility are both structure and sequence dependent but can be computationally predicted. We demonstrate this by reducing the aggregation of human a-galactosidase and protective antigen of Bacillus anthracis through mutation. Our results indicate that many proteins possess hot spots allowing to adapt protein solubility independently of structure and function.

3:35 Sponsored Presentation *(Opportunity Available)*

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 New Techniques for *In Vitro* Evolution and Selection of Enzymes
Manfred Konrad, Ph.D., Max-Planck Institute for Biophysical Chemistry, Head, Enzyme Biochemistry Laboratory
In this talk, I will present our strategy for generating and identifying enzyme variants displaying improved catalytic activity. In particular, I would present FACS and microfluidic techniques we developed for this purpose. I would explain experimental challenges associated with screening of enzyme libraries as opposed to the screening of libraries of antibodies and related binding molecules for which various display strategies (e.g. *E. coli*, yeast, ribosome, etc.) exist and proved generally highly successful, which are, however, not suitable for monitoring catalytic phenomena.

TRACK 2:
Protein Aggregation & Stability
蛋白质聚集和稳定性

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing

2:00 Chairperson's Remarks
Andrea Ji, Ph.D., Senior Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.

AGGREGATION FORMATION

2:05 Generating Artificial Aggregation-Associated Phenotype
Frederic Rousseau, Ph.D., Professor and Principal Investigator, Cellular and Molecular Medicine, VIB Switch Lab/University of Leuven
We present a method by which specific aggregation-associated phenotypes can be generated by inducing misfolding of endogeneous proteins using artificial peptides bearing aggregation prone sequences of the target protein. As a proof-of-concept we here show how targeted protein aggregation can be used to generate antitumoral and antimicrobial peptides but also transgenic plants.

2:35 Determinant Factor for Aggregation and Fragment Formation: Oxidation
Joy Zhou, Ph.D., Principal Scientist/Associate Director, DP MST, Shire
Formation of aggregation and subsequent subvisible particles is a major concern to develop subcutaneous biotherapeutics and understanding of its formation mechanism is challenging. Employing various biophysical techniques for structure integrity and physical/chemical testing enabled us to understand that oxidation can lead to formation of both soluble and insoluble aggregates, and subsequent formation of subvisible particles. Furthermore, the fragmentation is identified as a parallel degradation mechanism to aggregation/particle formation. More interestingly, a high concentration formulation exhibited much less degradation than the diluted one under this degradation mechanism.

3:05 Aggregation Analysis at High and Low Concentrations
Jennifer McManus, Ph.D., Lecturer, Department of Chemistry, National University of Ireland Maynooth
Aggregation of proteins may occur by a number of different mechanisms, which can lead to a range of aggregate types. Using a range of analytical techniques, the formation of protein aggregates by various mechanisms has been assessed at low and where possible, at moderate to high protein concentrations. The effect of sugars on protein stability will also be discussed.

3:35 Sponsored Presentation *(Opportunity Available)*

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

SOLUBILITY CHALLENGES

4:45 Specific Ion–Protein Interactions Dictate Solubility Behavior of a Monoclonal Antibody
Jifeng Zhang, Ph.D., Senior Director, Global Head of Device-ability, Global Biotherapeutics, Sanofi US

TRACK 1:
Protein & Antibody Engineering
蛋白质与抗体工程

5:15 Engineering G-Protein Coupled Receptors for High Production and Efficient Folding in Synthetic Environments
Frank Bernhard, Ph.D., Lab Manager, Biophysical Chemistry, Goethe University Frankfurt
Cell-free synthetic biology is an efficient tool for the fast generation of difficult protein targets such as G-protein coupled receptors or other important membrane proteins. We exemplify how to engineer membrane proteins for high cell-free expression and how to take advantage of the synthetic biology toolbox to modulate protein folding and stability. By comparing three different GPCR systems, common but also rather target-specific characteristics are identified.

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing

6:45 Close of Day One

WEDNESDAY, MARCH 29, 2017

8:30 Registration and Morning Coffee

8:50 Chairperson's Opening Remarks
Xiangyang Zhu, Ph.D., CEO, Huabo Biopharma (Shanghai) Co., Ltd.

DEVELOPMENT OF NOVEL BIOTHERAPEUTICS

9:00 Engineering Anti-VEGFR2 X Anti-PDGFR-Beta Bispecific Antibodies for the Treatment of Cancer and Ophthalmological Diseases
Zhenping Zhu, Ph.D., Executive Vice President, Global Biologics R&D, Kadmon Corp, LLC

9:30 Nexmab Antibody-Drug Conjugate for the Treatment of Ovarian Cancer
Sunbae Lee, Ph.D., Senior Research Scientist, R&D Center, Alteogen, Inc.
NexMab is a site-specific antibody-drug conjugate technology for the treatment of ovarian cancer. *In vitro*, *in vivo* efficacy and plasma stability of our NexMab ADC will be presented. Strategy for the treatment of ovarian cancer and the current state of the ADC development for ovarian cancer will also be presented.

10:00 Sponsored Presentation *(Opportunity Available)*

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

11:10 Advancing Bispecific Antibodies with Immune T Cells for Improved Treatment Efficacy
JianPing Qiu, Ph.D., Executive Vice President, YZY Biotherapeutics

11:40 Roundtable Discussion Session
Join your peers and exchange ideas and experiences in a lively and interactive discussion.

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing

2:00 Close of Protein & Antibody Engineering

TRACK 2:
Protein Aggregation & Stability
蛋白质聚集和稳定性

5:15 Modified Phosphate Buffered Saline (PBS) as a Viable Vehicle for Biotherapeutic Drugs
Tatyana Mezhebovsky, Ph.D., Principal Scientist, BioFormulations, Sanofi US
Phosphate buffered saline (PBS) is the most inert and neutral composition for biotherapeutics, however, notorious for freeze thaw instability, which makes a normal product life cycle for liquid formulations products virtually impossible. As lyophilization requires initial freezing of the protein solution, PBS is not suitable for lyo products. Here we present a systematic approach to PBS modification to render it a high quality vehicle for protein and potentially gene therapy products.

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing

6:45 Close of Day One

WEDNESDAY, MARCH 29, 2017

8:30 Registration and Morning Coffee

8:50 Chairperson's Opening Remarks
Mark Yang, Ph.D., Director, Fill Finish Operations, Biopharmaceutical Development, Genzyme

AGGREGATION CHALLENGES DURING FORMULATION

9:00 Protein Aggregation during Formulation and Drug Product Manufacturing and Mitigation Strategies
Mark Yang, Ph.D., Director, Fill Finish Operations, Biopharmaceutical Development, Genzyme
Proteins are subjected to many different forms of stresses, including agitation, freeze/thaw, light exposure, and oxidation, during formulation and fill finish operations. These stresses can destabilize protein and compromise drug product quality. Common stress factors and the corresponding mitigation strategies to minimizing protein aggregation during these processes will be discussed.

9:30 Challenges in Formulation Development of Bispecifics
Andrea Ji, Ph.D., Senior Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.

10:00 Sponsored Presentation *(Opportunity Available)*

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

11:10 Protein Aggregation: A Technical Challenge of Protein Drug Development and Manufacturing
Guangliang Greg Pan, Ph.D., Vice President, Technical Operations/CMC, MabSpace Biosciences (Suzhou) Co., Ltd.
Protein aggregation is one of the most critical stability concerns of protein drug development and manufacturing. This presentation will mainly cover the causing factors of and control strategies for protein aggregation during protein formulation development, manufacturing process, and clinical use. Several case studies will be included.

11:40 Roundtable Discussion Session
Join your peers and exchange ideas and experiences in a lively and interactive discussion.

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing

2:00 Close of Protein Aggregation & Stability

TRACK 3:
Immuno-Oncology
肿瘤免疫疗法

TRACK 4:
Analytical Characterization of Biotherapeutics
生物药物特性分析

1:00 pm Registration

PLENARY KEYNOTE SESSION

2:00 Chairperson's Opening Remarks
MingQiang Zhang, Ph.D., Head, R&D, Amgen Asia

2:05 Multimodal Cancer Therapy - Dynamic Process-Based Immuno-Oncology
Bertil Lindmark, M.D., Ph.D., CMO, ASLAN Pharmaceuticals

Novel immune-oncology approaches focusing on T-cell aggression have allowed a clear step change for several cancer forms. Therapies focused on other parts of the immune defense that take part in the immune shield of the tumor, like macrophages, dendritic cells, NK cells, and neutrophils may also be important. However, the classification and diagnosis of the immune processes at play in a given patient and methods to follow and steer immune based therapies are lacking in granularity, speed and interpretation. It is envisioned that novel treatment paradigms will be multi-modal and will need fast response gauging of tumor and systemic immune status, and will need to be designed according to dynamic evolution of immune response.

2:40 Rational Combination of Immune-Oncology Agents
Lei Zheng, Ph.D., Associate Professor, Oncology and Surgery, Gastrointestinal Cancer Program, Tumor Immunology Program, Johns Hopkins University

Combination immunotherapies are being developed with goals to overcome the resistance to the single agent checkpoint inhibitors and to enhance the depth and durability of the response to the ICIs. The combination of vaccine and immune checkpoint inhibitors may overcome the resistance to the immune checkpoint inhibitors as a single agent treatment. Other treatment modalities including radiation therapy and certain chemotherapeutic agents may also prime the immune quiescent tumors if immunogenic cell deaths can be induced by these treatment modalities. Immune modulators that target different aspects of T cell activation and exhaustion or target different cellular components are more likely synergized.

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

JOINT SESSION – ANALYTICAL CHARACTERIZATION FOR ENGINEERING T CELLS

3:50 Versatile Strategy for Controlling the Specificity and Activity of Engineered T Cells
Chan Hyuk Kim, Ph.D., Assistant Professor, Biological Sciences, KAIST

CD19-targeting chimeric antigen receptor (CAR) T cells have generated unprecedented responses in patients with refractory B-cell malignancies. However, the inability to control the activity of this potent "live" drug has resulted in severe treatment related toxicities and the constraint in targeting more than one antigen have limited its general application. In this talk, I will discuss our recent research efforts on addressing these limitations of current CAR-T therapy.

4:20 Applying a High Content Imaging Assay Platform to Elucidate the Mechanism of Actions of Cancer Immunotherapy
Ming Lei, Senior Research Investigator II, Lead Discovery and Optimization, Bristol-Myers Squibb Company

Understanding the spatiotemporal regulation of immuno-cell signaling network by drug candidates is essential for developing new cancer immunotherapy, designing rational combinational therapies and to differentiate amongst existing therapies. Here we describe how to leverage high-content image analysis to provide new insights for I-O drug selection and optimization, and use novel integrated solutions for fast in-depth analysis of I-O drug mechanism of actions.

PANEL DISCUSSION

4:50 Immunotherapy – Where Do We Stand Currently?
Moderator: Qingcong Lin, Ph.D., Vice President, Shenogen Pharma Group

- Immunotherapy current status, in metastatic melanoma and other solid tumors: Where do we stand currently?
- In addition to CTLA4, PD1, PDL1, what others have great potential, such as CD28, CD40CD40L, OX40/OX40L, 4-1BB/4-1BBL, CD27/CD70, LAG3, TIM3 and additional B7 molecules
- What are the major mechanisms for immunotherapy, macrophages, T cells, monocytes or dendritic cells?
- Combination approaches for immunotherapy, which combinations will make best sense? mAb/mAb and mAb/IDOi
- Toxicity will be a potential issue for combination immunotherapy, how could we select patients to minimize the adverse events, do we have good biomarkers in place?
- The *in vivo* and *in vitro* efficacy tests have been one of key issues for immunotherapy candidate selection, what models we need to develop for solving the issue?
- The potentials, strategies, and potential issues of oncolytical virus, CART, CD3 based bi-specific antibody, and small molecule immunomodulator technology
- The future of immunotherapy in oncology, what's currently on the horizon?

5:50 Close of Day Two

TRACK 3:
Immuno-Oncology
肿瘤免疫疗法

8:30 Morning Coffee

8:50 Chairperson's Opening Remarks
Jinming Gu, Ph.D., Executive Director, Biologics Discovery, Shanghai Hengrui Pharmaceutical Co., Ltd.

PIPELINE AND PROGRESS UPDATES IN CHINA'S IMMUNO-ONCOLOGY FIELD

9:00 Beyond PD-1: Challenge and Opportunity in Immuno-Oncology
Hongtao Lu, Ph.D., Executive Vice President & CSO, Discovery, Zai Laboratory

9:30 Anti-PD-1 Monoclonal Antibodies with IgG4 S228P, Functional Impact Mediated by Fc-Hinge Region
Kang Li, Ph.D., Head, Biologics, BeiGene, Ltd.
Utilizing anti-PD-1 antibodies to mobilize immune system for cancer eradication has been successful in treating certain types or subtypes of cancer including advanced melanoma, non-small cell lung cancer and renal cell carcinoma. Combining an anti-PD-1 antibody with other immune modulators has been investigated in expanding patient population with great potential. Most of anti-PD-1 antibodies in clinical trials are human IgG4 with S228P mutation (IgG4S228P). The secondary pharmacological functions mediated by the antibody Fc region are discussed.

10:00 Sponsored Presentation *(Opportunity Available)*

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

11:00 Targeted Delivery of Immunomodulators to Change Tumor Microenvironment
Ting Xu, Ph.D., CEO & President, AlphaMab Co.
A stable antibody-IL10 fusion molecule has been generated based on heterodimeric Fc scaffold. The molecule had been purified to high purity, retaining good antigen binding and IL10 activity. Comparing with IL10, the *in vivo* half-life has been improved to ~40hrs. The efficacy of the fusion protein has been tested in syngenic mouse tumor model. The fusion molecule induced tumor regression in mAb resistant tumor. Meanwhile, strong synergistic effect has been demonstrated with radio therapy. A preliminary study shows that targeted delivery of IL10 stimulated the expansion of established CD8+ CTL. Based on the results, CMC and IND enabling study of the fusion have been initiated and FIM is scheduled in Q1 of 2018.

11:30 Amgen's BiTE Bispecific T-Cell Engaging Antibody for Immunotherapy
MingQiang Zhang, Ph.D., Head, R&D, Amgen Asia

12:00 Sponsored Presentation
(Opportunity Available)

12:30 Networking Lunch in the Exhibit Hall with Poster Viewing

TRACK 4:
Analytical Characterization of Biotherapeutics
生物药物特性分析

8:30 Morning Coffee

8:50 Chairperson's Opening Remarks
Shan Chung, Ph.D., Senior Scientist and Group Leader, Bioanalytical Sciences, Genentech

OPTIMIZATION FOR EARLY STAGE/ PRECLINICAL DEVELOPMENT

9:00 Integrated Technology Solutions to Support Biologics Hit to Lead and Beyond
Han Li, Ph.D., Principal Scientist, Leads Discovery & Optimization, Bristol-Myers Squibb Company
By leveraging new detection technologies, novel assay and state of art automation capabilities, we have transformed the hybridoma discovery by implementing functional assays in early screening, thus greatly improving the antibody lead selection quality and speed. We developed innovative technology platforms to enable HT MOA studies and profiling across Itargets and leads. We have also built a core team to feed bioassays and accelerate program transition from discovery to development.

9:30 Mutational Approaches to Improve the Biophysical Properties of Single Domain Antibodies
Jamshid Tanha, Ph.D., Senior Research Officer, Human Health Therapeutics Portfolio, National Research Council Canada
Various mutational approaches for improving the biophysical properties of VH and VL single-domain antibodies have been described. Here we zoom in on one particular approach, namely disulfide engineering approach, which improves the stability VHs and VLs. The approach appears to be universally applicable across all VHs and VLs and may also apply to scFvs, Fabs, mAbs and their derivatives.

10:00 Sponsored Presentation *(Opportunity Available)*

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

11:00 Efficient and Fit-For-Purpose Bioanalytical Support for Non-Clinical Biotherapeutic Development
Yanmei Lu, Ph.D., Scientist, Biochemical and Cellular Pharmacology, Genentech, Inc.
Bioanlytical support for biotherapeutics at discovery and preclinical stage is highly dynamic and fast paced. It involves developing and validating assays to test multiple candidate molecules in different animal species and samples matrices. Several strategies of increasing lab efficiency will be discussed, including fit-for-purpose assay validation, multiplexing and the use of generic immunoassay and automation.

11:30 How to Optimize Stability of Drug Substance and Drug Product through Integration of Rapid and Sensitive Analytical Tools with Rational Approach to Developability Assessment and Early Formulation Development
Danny Chou, Ph.D., President, Compassion BioSolutions, LLC
Therapeutic proteins are challenging to develop and manufacture because their marginal stability makes them prone to denaturation and aggregation during purification, storage, distribution, and administration. While there is an absence of a definitive strategy that can prevent these instabilities against all forms of stress, we are at the dawn of a new era with the emergence of new analytical tools that can enable both prediction and real-time monitoring of protein stability. The goal of this presentation is to share how one can integrate these new tools with an advanced Design of Experiments (DOE) approach to generate maximum information even when under great time and material constraints.

12:00 Affinity & Stability: VIPs in the Analytical Characterization of Biotherapeutics
Sponsored by NanoTemper Technologies
Zhuo Li, Ph.D., Application Specialist, NanoTemper Technologies
To develop biotherapeutics, two very important parameters (VIPs) needs to be checked and optimized: binding affinity and protein stability. Learn how to make better informed decisions early in the biotherapeutics development workflow with MicroScale Thermophoresis and nanoDSF and thus to significantly reduce time-to-market.

12:15 Sponsored Presentation *(Opportunity Available)*

12:30 Networking Lunch in the Exhibit Hall with Poster Viewing

TRACK 3:
Immuno-Oncology
肿瘤免疫疗法

1:45 Chairperson's Remarks
Ting Xu, Ph.D., CEO & President, AlphaMab Co.

1:50 Improving the Efficacy of Immuno-Checkpoint Inhibitor through Target Mediated Antibody Recycling and Combination Interventions
Xueming Qian, Ph.D., Chairman & CEO, MabSpace Biosciences (Suzhou) Co., Ltd.
Checkpoint inhibition is a promising approach with durable responses. However, the depth of the responses is influenced by the number of activated T cells present, the amount and time of antibody staying in the tumor and the presence of immune-suppressive tumor microenvironment. We developed a PD-L1 antibody with target mediated recycling. The *in vivo* activity of this antibody alone or in combination with antibodies targeting tumor microenvironment will be presented.

2:20 Screening PD1 Inhibitors and Beyond
Bo Chen, Ph.D., CEO, Shanghai Junshi

2:50 The Design and Development of Novel Biologics for Cancer Immunotherapies
Jinming Gu, Ph.D., Executive Director, Biologics Discovery, Shanghai Hengrui Pharmaceutical Co., Ltd.
Cancer immunotherapies have brought hope to many cancer patients worldwide, who have failed traditional chemo- and/or targeted therapies. While showing promise in the clinics, the current limitation of anti-CTLA-4 or anti-PD-1 therapies is low response rate and high toxicity. Next generation cancer immunotherapies will focus on combination therapies. Bispecific antibodies offer a number of exciting opportunities. This presentation will cover a few late stage pre-clinical bispecific programs for cancer immunotherapies.

3:20 Sponsored Presentation *(Opportunity Available)*

3:50 Novel Bispecific Antibody Technology for Cancer Immunotherapeutics
Chengbin Wu, Ph.D., CEO, Epimab

4:20 Developing Biologics for Patients
Guoqing Cao, Ph.D., Vice President, Jiangsu Hengrui

4:50 Selection of Fc for Antibody Therapeutics to Achieve Optimal Antitumor Immunomodulating Activity
Jieyi Wang, Ph.D., CEO, Lyvgen Biopharma
Therapeutic antibodies have become important biologics for cancer immunotherapy. Their modes of action not only rely on variable domains responsible for specificity but also involve the constant domains that can interact with various Fc receptors. Blocking antibodies such as nivolumab and pembrolizumab were successfully developed in the clinic as IgG4 molecules. However, it is not clear what IgG isotypes would be optimal for agonist antibodies that are required to activate co-stimulatory targets such as CD40, OX40, CD27, CD137, GITR, ICOS and HVEM.

5:20 Close of Conference

TRACK 4:
Analytical Characterization of Biotherapeutics
生物药物特性分析

1:45 Chairperson's Remarks
Danny Chou, Ph.D., President, Compassion BioSolutions, LLC

STRUCTURE FUNCTION CHARACTERIZATION OF NOVEL AND BIOSIMILAR PRODUCTS

1:50 Effects of Glycosylation on Biological Activities of Therapeutic Antibodies
Shan Chung, Ph.D., Senior Scientist and Group Leader, Bioanalytical Sciences, Genentech
This talk will present background on glycosylation and glycoform variants in mAbs produced from CHO cells, and will discuss common methods for characterization of N-linked glycosylation in mAbs. We'll also explore the effect of glycosylation on pharmacokinetics and biological activities of mAbs.

2:20 Higher Order Structure Analysis of Antibodies by Hydrogen/Deuterium Exchange Mass Spectrometry
Susumu Uchiyama, Ph.D., Associate Professor, Graduate School of Engineering, Osaka University
Assessment of higher order structure (HOS) of proteins is important for its concrete characterization. Here our recent studies on monoclonal antibody (mAb) HOS using hydrogen/deuterium exchange mass spectrometry (HDX-MS) will be introduced. Structural comparison of mAbs in different solution conditions, structural analysis of mAbs aggregates and epitope determination will be demonstrated. Our data strongly indicate that HDX-MS is highly effective and powerful for the HOS analysis for both innovative therapeutic proteins and biosimilars.

2:50 Physicochemical and Functional Characterization of a Biosimilar Bevacizumab
Ravish Patel, Ph.D., Scientist, Bioanalytical (Biologics), Analytical Development Lab, EPR Centre for Cancer Research and Bioinformatics Pvt. Ltd., India
The biological activity and clinical profile of mAb therapeutics, including Bevacizumab, is influenced by their protein structure and glycosylation patterns, which can be affected by the expression system, cell culture conditions and purification process methodology. While clinical outcome cannot yet be attributed to many of the individual structural features that constitute a mAb, it is evident that detailed structural attribute analysis is necessary if structural contributions to function are to be comprehensively defined. Bevacizumab product quality data generated are presented here. These data reveal a consistent and tightly controlled profile for the product.

3:20 How Similar is My Biosimilar? A LC and MS Prospective
Sponsored by Waters THE SCIENCE OF WHAT'S POSSIBLE.
John C. Gebler, Ph.D., Director, Biopharma Business Development, Waters Corporation
Additional incentive has come from reducing the cost and increasing global access to life-saving therapies for patents. Biologic drugs are inherently homogeneous and innovator products are often a composite of similar species manufactured within a specific range of variability. Drug manufactures and regulators want to reduce risks to patients and ensure that biologics and safe and efficacies. The presentation will report on the use of LC/MS for in-depth, reproducible, and meaningful characterization/comparability between an innovator and biosimilar.

3:50 Bioassay Lifecycle: From Development to Continuous Verification
Gael Debauve, Ph.D., Associate Director, Bioassay Development, UCB
Biological activity is a critical quality attribute for biopharmaceutical products and cell-based bioassays are generally used to accurately determine this activity. The case study will go through the method development journey: from the development itself to the tools implemented to monitor the method performance.

4:20 Sequence Variants of Recombinant Antibody Therapeutics
Zhihua Julia Qiu, Ph.D., Vice President, R&D, Qyuns Therapeutics, Inc.
Sequence variants in recombinant biopharmaceuticals are a concern during the production of recombinant human monoclonal antibodies. Hence, detection of potential sequence variants during clone selection and bioprocess development are important to the biopharma industry. How these product-related sequence variants arise, the overall risk, and approaches to detecting sequence variants will be discussed.

4:50 USP Compendial Approaches to Characterization of Biologics
Yi Huang, Ph. D., Senior Manager of SCD, Biologics, USP-China

5:20 Close of Conference

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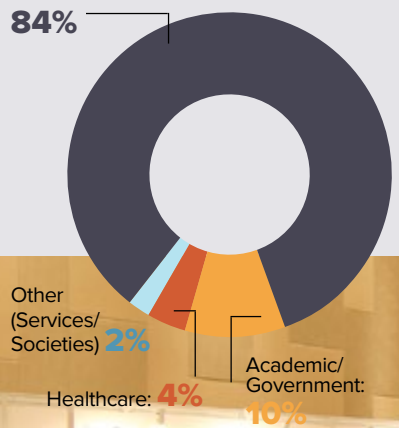

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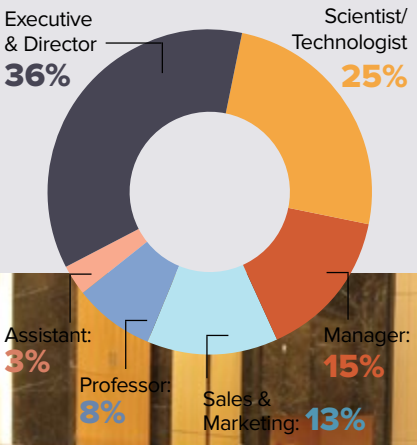

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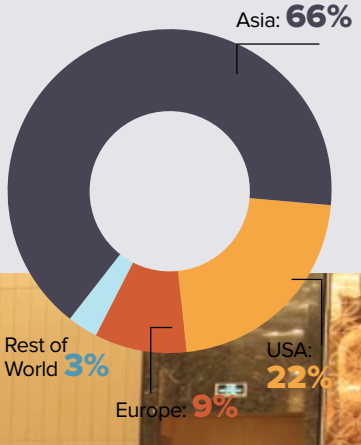

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