

# Antibody Engineering

Scientific Sponsor:  
The Antibody Society

## Keynote Presentations

### *Evolving Technologies of Antibody Engineering*



**Michael S. Neuberger, Ph.D.**

*Head, Division of Protein and  
Nucleic Acid Chemistry, MRC Laboratory of  
Molecular Biology, United Kingdom*

### *Antibodies: Versatile Proteins for Multiple Applications*



**Sherie Morrison, Ph.D.**

*Chair, Department of Microbiology,  
Immunology, & Molecular Genetics,  
University of California, Los Angeles*

## *Antibody Engineering and Immunotherapeutics for the 21st Century*

Program Agenda: Pages 5-12

## **Cutting-Edge Presentations from a Preeminent Internationally Recognized Faculty**

- Microarrays and Nanotechnology for Antibody Discovery and Analysis
- The Single-Chain Fv and its Fusion Proteins: 20 Years Old and Coming of Age
- The Theory, Practice and Use of Libraries Based on Restricted Amino Acid Sets
- Are Non-Antibody Scaffolds Really any Better than Antibody Fragments?
- Intrabodies Revisited
- Novel Antibody Targets and Applications
- Antibodies in a Complex Environment: Target Selection in Relation to Efficacy
- Mechanism of Antibody Action Revisited

Co-located Event: IBC's 6th Annual

December 9-11, 2008

# Antibody Therapeutics

*Advancing Therapeutic Antibodies; Tracking  
Preclinical and Clinical Development; the Antibody  
Business Climate; Intellectual Property Updates*

Program Agenda: Pages 13-17

## Antibody Engineering Distinguished Faculty

Franz Josef Baudenbacher, Ph.D.  
**Vanderbilt University**

Richard H.J. Begent, M.D.  
**University College London,**  
*United Kingdom*

Ramesh R. Bhatt, Ph.D.  
**Sea Lane Biotechnologies**

Ezio Bonvini, M.D.  
**MacroGenics, Inc.**

Darryl J. Bornhop, Ph.D.  
**Vanderbilt University**

Carl A.K. Borrebaeck, Ph.D.  
**Lund University, Sweden**

Andrew Bradbury, M.B., B.S., Ph.D.  
**Los Alamos National Laboratories**

Alexandre G. Brolo, Ph.D.  
**University of Victoria, Canada**

Dennis R. Burton, Ph.D.  
**The Scripps Research Institute**

Antonino Cattaneo, Ph.D.  
**European Brain Research**  
**Institute, Italy**

Lieping Chen, M.D., Ph.D.  
**Johns Hopkins University**  
**School of Medicine**

Anne S. De Groot, Ph.D.  
**EpiVax**

Erik W. Debler, Ph.D.  
**Rockefeller University**

Eric Furfine, Ph.D.  
**Adnexus**

Jaap Goudsmit, M.D., Ph.D.  
**Crucell NV, The Netherlands**

John Haurum, M.D.  
**Symphogen, Denmark**

James S. Huston, Ph.D.  
**EMD Serono Research Center**

Kim D. Janda, Ph.D.  
**The Scripps Research Institute**

Laurent S. Jaspers, Ph.D.  
**Domantis Limited, United**  
**Kingdom**

Hiroyuki Kishi, Ph.D.  
**University of Toyama, Japan**

Shohei Koide, Ph.D.  
**University of Chicago**

Evert J. J. Kueppers  
**Pieris AG, Germany**

Dasa Lipovsek, Ph.D.  
**Codon Devices, Inc.**

J. Christopher Love, Ph.D.  
**Massachusetts Institute of**  
**Technology**

Wayne A. Marasco, M.D., Ph.D.  
**Harvard Medical School**

James D. Marks, M.D., Ph.D.  
**University of California,**  
**San Francisco**

Andrew Martin, D.Phil.  
**University College London,**  
*United Kingdom*

David J. Mauro, M.D., Ph.D.  
**Bristol Myers Squibb**

Kendall M. Mohler, Ph.D.  
**Trubion Pharmaceuticals**

Sherie Morrison, Ph.D.  
**University of California,**  
**Los Angeles**

Serge Muyldermans, Ph.D.  
**Vrije University, Belgium**

Dario Neri, Ph.D.  
**ETH Zürich, Switzerland**

Michael S. Neuberger, Ph.D.  
**MRC Laboratory of Molecular**  
**Biology, United Kingdom**

Ulrik B. Nielsen, Ph.D.  
**Merrimack Pharmaceuticals**

R. Barbara Pedley, Ph.D.  
**UCL Cancer Institute,**  
*United Kingdom*

Manuel L. Penichet, M.D., Ph.D.  
**University of California,**  
**Los Angeles**

Andreas Plückthun, Ph.D.  
**University of Zürich, Switzerland**

Josef Prassler, Ph.D.  
**MorphoSys AG, Germany**

Terence H. Rabbitts, Ph.D.  
**Leeds Institute of Molecular**  
**Medicine, United Kingdom**

Jeff Ravetch, Ph.D.  
**Rockefeller University**

Walter Schubert, M.D.  
**University of Magdeburg, Germany**

Jamie K. Scott, M.D., Ph.D.  
**Simon Fraser University, Canada**

David L. Selwood, BSc, CSci,  
FRSC, CChem  
**University College London,**  
*United Kingdom*

Sachdev Sidhu, Ph.D.  
**University of Toronto,**  
*Canada*

Michael Sierks, Ph.D.  
**Arizona State University**

Willem 'Pim' Stemmer, Ph.D.  
**Amunix Inc.**

Duxin Sun, Ph.D.  
**University of Michigan**

Ian M. Tomlinson, Ph.D.  
**GSK-Domantis Group,**  
*United Kingdom*

Joseph M. Tuscano, M.D.  
**University of California, Davis**

Jan Van den Brulle, Ph.D.  
**Sloning BioTechnology GmbH,**  
*Germany*

Eric Vives, Ph.D.  
**University of Montpellier, France**

Louis M. Weiner, M.D.  
**Georgetown University**  
**Medical Center**

Anthony Williamson, Ph.D.  
**Calmune**

## Antibody Therapeutics Distinguished Faculty

Mark R. Alfenito, Ph.D.  
**KaloBios Pharmaceuticals Inc.**

Patrick A. Baeuerle, Ph.D.  
**Micromet, Inc.**

Tim Bourne, Ph.D.,  
**UCB Cell, United Kingdom**

Michael Braunagel, Ph.D.  
**Affitech AS, Norway**

Benjamin P. Chen, Ph.D.  
**Burrill & Company**

Steve Coats, Ph.D.  
**MedImmune, Inc.**

Rathin C. Das, Ph.D.  
**Affitech USA, Inc.**

Robert O. Dillman, M.D.  
**University of California, Irvine**

Jonathan G. Drachman, M.D.  
**Senior Medical Director, Seattle**  
**Genetics**

David M. Feltquate, M.D., Ph.D.  
**Bristol-Myers Squibb Co.**

Gilles Gallant, B.Pharm. Ph.D.  
**Human Genome Sciences, Inc.**

Scott M. Glaser, Ph.D.  
**Biogen Idec, Inc.**

Roland Kolbeck, Ph.D.  
**MedImmune, Inc.**

John A. Latham, Ph.D.  
**Alder Biopharmaceuticals**

Stanley Lewis, M.D.  
**Taimed Biologics**

John C. Lin, M.D., Ph.D.  
**Rinat, Pfizer Inc.**

Nils Lonberg, Ph.D.  
**Medarex, Inc.**

Israel Lowy, M.D., Ph.D.  
**Medarex, Inc.**

William C. Olson, Ph.D.  
**Progenics Pharmaceuticals, Inc.**

Paul W.H.I. Parren, Ph.D.  
**Genmab, The Netherlands**

Tillman Pearce, Ph.D.  
**KaloBios Pharmaceuticals Inc.**

Thomas A.E. Platts-Mills, M.D.,  
Ph.D.  
**University of Virginia**

Dale B. Schenk, Ph.D.  
**Elan Pharmaceuticals, Inc.**

Petra M. Schmitt, Ph.D.  
**Paul-Ehrlich-Institute, Germany**

Timothy J. Shea, Jr.  
**Sterne, Kessler Goldstein & Fox**  
**P.L.L.C.**

Philip E. Thorpe, Ph.D.  
**University of Texas Southwestern**  
**Medical Center**

Pablo Umana, Ph.D.  
**Glycart-Roche, Switzerland**

Trudi Veldman, Ph.D.  
**Abbott Laboratories**

Diane Wilcock, Ph.D.  
**Xoma (US) LLC**

Herren Wu, Ph.D.  
**Medimmune, Inc.**

Zhenhua (Mike) Xu, Ph.D., F.C.P.,  
**Centocor R&D/Johnson**  
**& Johnson**

Jennifer A. Zarutskie, Ph.D., J.D.  
**Dyax Corp.**

Zhenping Zhu, M.D., Ph.D.  
**ImClone Systems Incorporated**

Eugene Zhukovsky, Ph.D.  
**Xencor**

## Sunday, December 7, 2008

Afternoon	Pre-Conference Workshop: <b>Microarrays and Nanotechnology for Antibody Discovery and Analysis</b>	 Purchase the all access pass to attend the Sunday workshop and Monday sessions of Antibody Engineering – <b>AND SAVE!</b>
5:30 pm	<b>The Antibody Society:</b> General Session (see page 5 for information)	

## Monday, December 8, 2008

Exhibit Hall Hours: 6:00 pm - 7:30 pm

Morning	Session I: <b>Keynote Presentations</b> <b>Michael S. Neuberger, Ph.D.</b> , Head, Division of Protein and Nucleic Acid Chemistry, MRC Laboratory of Molecular Biology, United Kingdom <b>Sherie Morrison, Ph.D.</b> , Chair, Department of Microbiology, Immunology, & Molecular Genetics, University of California, Los Angeles	
1:15 pm	Technology Workshops: Bio-Rad Laboratories, MedImmune	
1:45 pm	Technology Workshop: Codon Devices, XOMA, Ltd.	
Afternoon	Session II: <b>The Single-Chain Fv and its Fusion Proteins: 20 Years Old and Coming of Age</b>	
6:00 pm	Networking Cocktail Reception, Opening of Poster and Exhibit Hall	

## Tuesday, December 9, 2008

Exhibit Hall Hours: 9:30 am – 7:45 pm

Morning	Session III: <b>The Theory, Practice and Use of Libraries Based on Restricted Amino Acid Sets</b>	Start of Antibody Therapeutics Session I: <b>Preclinical Development of Antibody Therapeutics</b> Keynote Presentation: <b>Benjamin P. Chen, Ph.D., Burrill &amp; Company</b>
11:45 am	Technology Workshops: Antitope, Percivia LLC	
12:15 pm	Networking Luncheon, Exhibit and Poster Viewing	
1:45 pm	Technology Workshops: Attana AB, MorphoSys AG	
Afternoon	Session IV: <b>Are Non-Antibody Scaffolds Really Any Better than Antibody Fragments?</b>	Session II: <b>Clinical Development of Cancer Therapeutics (1)</b> Keynote Presentation: <b>Robert O. Dillman, M.D., Hoag Cancer Center</b>
6:15 pm	Networking Cocktail Reception, Exhibit and Poster Viewing	

## Wednesday, December 10, 2008

Exhibit Hall Hours: 9:45 am - 2:00 pm

Morning	Session V: <b>Intrabodies Revisited</b>	Session III: <b>Clinical Development of Cancer Therapeutics (2)</b>
12:00 pm	Technology Workshop: BioWa	
12:30 pm	Networking Luncheon, Last Chance for Exhibit and Poster Viewing	
Afternoon	Session VI: <b>Novel Antibody Targets and Applications</b>	Session IV: <b>Clinical Development of Non-Cancer Therapeutics (1)</b>

## Thursday, December 11, 2008

Morning	Session VII: <b>Antibodies in a Complex Environment: Target Selection in Relation to Efficacy</b>	Session V: <b>Clinical Development of Non-Cancer Therapeutics (2)</b> <i>Antibody Therapeutics Ends</i>
Afternoon	Session VIII: <b>Mechanism of Antibody Action Revisited</b>	

## Student Poster Scholarship Program

To support the education and professional development of students working toward careers in antibody engineering-related disciplines, IBC Life Sciences and The Antibody Society will offer ten complimentary registrations and posterboard spaces for this year's Antibody Engineering conference. The recipients will be selected by the Society's board of directors, and each student chosen will present their poster in the Antibody Engineering poster hall and receive complimentary registration for the full five-day conference. Eligibility requirements and instructions on how to participate are shown below:

- Student must be a full-time graduate student at a university or academic research institute
- Post-doctoral researchers are not eligible
- Poster abstracts must be submitted no later than **Friday, October 24, 2008** at: [www.IBCLifeSciences.com/Antibodyeng](http://www.IBCLifeSciences.com/Antibodyeng)
- Winners will be notified by **Friday, November 14, 2008** – and those not awarded a complimentary registration will receive a discount to attend the meeting
- The award includes a complimentary full registration to the conference and pre-conference workshop. Travel and lodging expenses are the responsibility of the recipient

# Antibody Engineering

*Antibody Engineering and Immunotherapeutics for the 21st Century*

During the 1980's, antibody engineering emerged as a new discipline through a progression of scientific breakthroughs. This year's Keynote speakers have been leading pioneers in this field since its beginning, having contributed many of the advancements that engendered the current revolution in recombinant antibodies and their successful clinical application, making antibody therapy a major new area of modern medicine. Dr. Michael S. Neuberger, Ph.D., from the MRC Laboratory of Molecular Biology, will discuss the evolving technologies of antibody engineering, and Professor Sherie Morrison, Ph.D., from UCLA, will discuss the versatility of antibodies for multiple applications.

In 1990, the first IBC International Conference on Antibody Engineering was held to promote interactions within this embryonic field and it has since become a hallmark of the field, by promoting personal interaction and presenting singular advances in antibody engineering, related binders, and resulting therapeutics. **This year's 19th International Conference continues this tradition of major themes, with a dramatic expansion of presentations selected by the Scientific Advisory Board.** The Antibody Society is the Scientific Sponsor of the Conference, which underscores the role of this meeting as a forum for the antibody engineering community.

During the five days of the conference, an unparalleled international faculty of more than 60 leading scientists will present their latest research results on advances in basic and applied antibody and binder engineering, and their therapeutic development. Participants will be able to network with more than 700 colleagues, explore exhibits showcasing new research technologies, and interact with speakers as well as poster authors.

As a delegate for the Antibody Engineering meeting, you may also attend the sessions of the **6th Annual Antibody Therapeutics** conference at no additional charge. This three-day program runs concurrent with Antibody Engineering from Tuesday-Thursday (December 9-11), and presentations feature over twenty updates on clinical and preclinical stage industry antibody programs, business and legal updates and much more! To view the complete program, please see pages 13-17.

## Antibody Engineering Scientific Advisory Board

**Richard H.J. Begent, M.D.**, *Head of Oncology, Ronald Raven Professor of Oncology, University College London, United Kingdom*

**Andrew Bradbury, M.B., B.S., Ph.D.**, *Research Scientist, Los Alamos National Laboratories*

**Dennis R. Burton, Ph.D.**, *Professor, Immunology Department, The Scripps Research Institute*

**James S. Huston, Ph.D.**, *Vice President and Senior Research Fellow, EMD Serono Research Center*

**James D. Marks M.D., Ph.D.**, *Professor of Anesthesia and Pharmaceutical Chemistry, University of California, San Francisco*

**Andreas Plückthun, Ph.D.**, *Professor of Biochemistry, Department of Biochemistry, University of Zürich, Switzerland*

**Jamie K. Scott, M.D., Ph.D.**, *Professor and Canada Research Chair in Molecular Immunity, Department of Molecular Biology & Biochemistry, Simon Fraser University, Canada*

**Ian M. Tomlinson, Ph.D.**, *Vice President, GSK-Domantis Group, United Kingdom*

**Louis M. Weiner, M.D.**, *Director, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center*

## Microarrays and Nanotechnology for Antibody Discovery and Analysis

12:00 *Registration Opens*

### 1:30 **Announcements and Chairperson's Opening Remarks**

**Jamie K. Scott, M.D., Ph.D.**, *Professor and Canada Research Chair in Molecular Immunity, Department of Molecular Biology & Biochemistry, Simon Fraser University, Canada*

### Nanosensors

#### 1:45 **A New Generation of Nanostructures for SPR Biosensing and Antibody Research**

Surface plasmon resonance (SPR) is a widely used technology to determine binding events involving biological species. We will discuss a new type of SPR sensing technology based on nanostructured holes milled on gold films. This new SPR substrate allows measurements in transmission mode, which is ideal for microarray implementation. Moreover, the nanoholes allow further advantages over the current SPR technology in terms of sensitivity and solution delivery.

**Alexandre G. Brolo, Ph.D.**, *Associate Professor, Department of Chemistry, Department of Chemistry, University of Victoria, Canada*

#### 2:15 **Detection of Cellular and Chemical Activity in Nanoliter Volumes**

Micromachined devices and microfluidics allow for a dramatic reduction of the reaction volume or the confinement of single cells into *in vivo* like microenvironments. We describe a micromachined Nanocalorimeter to measure the heat generation of chemical reactions or the contraction of cardiac myocytes with nW sensitivity in nanoliter volumes, and a Nanophysiometer, which allows us to trap single cells in chemically controlled nanoliter volumes to measure extracellular acidification and glucose consumption rates, intracellular pH and pCa under physiologically relevant conditions.

**Franz Josef Baudenbacher, Ph.D.**, *Assistant Professor, Department of Biomedical Engineering, Vanderbilt University*

#### 2:45 **Molecular Interaction Studies using Backscattering Interferometry**

Interferometry is an optical sensing method that has recently been transformed into an ultra-high sensitivity, picoliter volume biosensor. Backscattering interferometry (BSI) employs a simple optical train that consists of a coherent, collimated source, a channel in a microfluidic chip containing a sample, and a position sensing transduction system. BSI is described in detail, and the potential of BSI to be used as an assay platform for performing antibody-antigen interaction assays rapidly, with exceedingly small sample quantities, is demonstrated.

**Darryl J. Bornhop, Ph.D.**, *Professor, Department of Chemistry, Vanderbilt University*

3:15 *Networking Refreshment Break*

### Antibodies for Detection

#### 3:45 **A Blue-Luminescent Antibody: Mechanism and Applications**

Antibodies elicited against trans-stilbene have resulted in luminescent complexes that can be harnessed for various biosensor applications. Due to its extremely bright blue luminescence, antibody EP2-19G2 has been of particular interest for mechanistic studies and for its development in biosensor assays. Its structure and light-generating mechanism, as well as several potential applications, will be discussed.

**Erik W. Debler, Ph.D.**, *Postdoctoral Fellow, Rockefeller University*

### Cell Microarrays

#### 4:15 **Microwell Arrays for Detecting Single, Antigen-Specific B-lineage Cells**

We have developed a highly integrated live-cell microarray system for analyzing the cellular responses of individual cells using a microwell-array chip that has up to 234,000 microwells each of which is just large enough to fit a single cell. We have applied the system to detect human antigen-specific B-cells or antibody secreting cells. Our system can produce antigen-specific human monoclonal antibodies from PBL in a week.

**Hiroyuki Kishi, Ph.D.**, *Associate Professor, Department of Immunology, Graduate School of Medicine and Pharmaceutical Sciences, University of Toyama, Japan*

#### 4:45 **Engraved Microarrays for Detecting Single, Antigen-Specific Cells**

This talk will describe a soft lithographic technique that uses an array of subnanoliter containers to isolate large numbers of individual antibody-secreting cells and print protein microarrays of the corresponding antibodies from each cell. The method enables rapid, high-throughput screening (>106 cells/day) and yields many characteristics of the antibodies in the primary screen, including the specificity, isotype, and affinity of each clone.

**J. Christopher Love, Ph.D.**, *Assistant Professor, Chemical Engineering, Texaco-Mangelsdorf Career Development Professor in Chemical Engineering, Massachusetts Institute of Technology*

5:15 *Close of Workshop Session; Start of Antibody Society General Session*

## Special Evening Meeting

Sunday, December 7, 2008

### The Antibody Society: General Session and Discussion of Specific Initiatives on the Preservation and Advancement of Informatics Resources for the Antibody Engineering Field

*(Open to all registered delegates for Antibody Engineering and Antibody Therapeutics. Workshop registration is not required.)*

The Antibody Society was formed in 2007 to broadly further the interests of antibody and binder engineering as well as antibody/binder therapeutic development, to ensure advancement of the field while maintaining the safe and thorough testing of future therapeutic agents in our field. The official journal of the Society is PEDS (Protein Engineering, Design and Selection), and members receive a special discount to this and most meetings scientifically sponsored by the Society. The Society represents this increasingly diverse field by supporting the resources that promote successful engineering of recombinant antibodies, single scaffold binders, and other facets of basic and applied research by those in academics and the private sector. The Society also seeks to provide a forum and voice for all aspects of this global field. By joining The Antibody Society, members will help the Society support its goals, including the following:

- To encourage participation at important meetings in our field
- To establish committees that will assess topics of urgency, often including open discussion within our community
- To develop guidelines that help to ensure the safety of antibody-related therapeutics, during preclinical and clinical testing, and beyond
- To work for development and acceptance of formats for the interoperability of data, databases, and computational resources underpinning this field
- To work for the support, maintenance, and improvement of other critical resources in this field
- To develop mechanisms that encourage the training and funding of students, postdocs, and others in this field

For further information on how you and your organization can join the Society, please visit the Society website: [www.AntibodySociety.org](http://www.AntibodySociety.org)

7:30 Registration, Networking Coffee

8:00 Announcements

### Session I: Keynote Presentations

#### 8:15 Chairperson's Opening Remarks and Keynote Introduction

**Dennis R. Burton, Ph.D.**, Professor, Immunology Department, The Scripps Research Institute

#### Keynote Presentation

##### 8:30 Evolving Technologies of Antibody Engineering

Multiple technologies underpin the derivation of the different monoclonal antibodies currently used in therapy. However, the derivation of many of these mAbs has ultimately relied on the *in vivo* processes of antibody gene diversification and antigen-mediated selection in order to obtain the initial antigen combining site: this primary antibody has then usually been refined or humanized by *in vitro* engineering. Here, I will review the recent advances in our understanding of the normal physiological processes of antibody generation and maturation with a view to how these processes have or can be exploited for the generation of engineered antibodies.

**Michael S. Neuberger, Ph.D.**, Head, Division of Protein and Nucleic Acid Chemistry, MRC Laboratory of Molecular Biology, United Kingdom



9:30 Audience Questions

9:45 Networking Refreshment Break

#### 10:15 Keynote Introduction by Session Chair

#### Keynote Presentation

##### 10:30 Antibodies: Versatile Proteins for Multiple Applications

Because of their unique properties, antibodies are ideal for many applications. They recognize their targets with exquisite specificity and high affinity. They are comprised of discrete functional domains. This domain structure of antibodies facilitates their genetic manipulation and makes it possible to produce diverse antibody-related proteins for many different applications. Antibodies exist as different isotypes with different properties. They bind Fc receptors and can activate the complement cascade, leading to important functional outcomes. They have a long half-life that can be manipulated. Antibodies are glycoproteins, with the structure of their attached carbohydrate making important contributions to their functional properties. Antibodies retain their essential characteristics when fused to a wide range of non-antibody proteins.

**Sherie Morrison, Ph.D.**, Chair, Department of Microbiology, Immunology, & Molecular Genetics, University of California, Los Angeles



11:30 Audience Questions

11:45 Lunch on Your Own

#### 1:15 Technology Workshops

##### Using the ProteOn to Characterize Antigen/Antibody Interactions

**BIO-RAD**

The ProteOn is a parallel-processing surface plasmon resonance biosensor that can address 36 interactions per binding cycle in a 6 by 6 format through the use of its unique crisscrossing flow paths. In a single injection, it can measure the kinetics of an analyte binding to six different ligands on the chip, without the need for regeneration. Multiplexing assays in this way is particularly useful in other applications, such as blocking.

**Yasmina Abdiche, Ph.D.**, Senior Principal Scientist, Rinat Laboratories, Pfizer Inc.

##### Reconstituted Ribosome Display for Efficient Evolution of Antibody Affinity

**MedImmune**

This abstract was not available at the time of printing the brochure. For up to date program information, please visit [www.IBCLifeSciences.com/Antibodyeng](http://www.IBCLifeSciences.com/Antibodyeng)

**Lutz Jermutus, Ph.D.**, Senior Director of Technology, MedImmune, United Kingdom

#### 1:45 Technology Workshops

##### Synthetic Biology and Secretion-Capture Display in Antibody Engineering

**CODON DEVICES**

We will describe advances in construction of extremely high-fidelity synthetic libraries, and in display technologies for selection of antibodies from such libraries. These include large synthetic variant libraries with error rates lower than 1 in 3,000 base pairs, and a novel, secretion-and-capture display method, which allows *in-vitro* selection of even complex, disulfide-bonded proteins, such as full-length IgG. We will also describe an application of these technologies to affinity maturation of antibodies.

**Dasa Lipovsek, Ph.D.**, Director of Protein Engineering, Codon Devices, Inc.

##### A Custom-Designed Approach to Antibody Discovery

**XOMA**  
A Leader In Therapeutic Antibodies

Through a series of strategic cross-licensing relationships and internal innovation, XOMA has created a premier Ab technology platform. It is comprised of six commercial human Ab phage display libraries and custom libraries for Ab discovery, proprietary Human Engineering™ and Ab optimization technologies, and an integrated product development infrastructure. The success of this approach is illustrated with XOMA 052, a 300fM mAb currently in Phase I clinical testing.

**Linda Masat, Ph.D.**, Director, Antibody Discovery and Engineering, XOMA, Ltd.

2:15 Announcements

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## Session II: The Single-Chain Fv and its Fusion Proteins: 20 Years Old and Coming of Age

### 2:20 Chairperson's Opening Remarks

**James S. Huston, Ph.D.**, *Vice President and Senior Research Fellow, EMD Serono Research Center*

### 2:30 Engineered MFE-23 scFv Fusion Proteins for ADEPT Cancer Therapy and Systems Medicine

Antibody-directed enzyme prodrug therapy (ADEPT) has been developed using a single chain Fv fused to carboxypeptidase G2 that is glycosylated in *Pichia pastoris*. Enzyme is targeted to tumor where it generates a cytotoxic drug through activation of a harmless prodrug. The approach to developing a complex therapy has been formalized in guidelines for information about antibody therapy.

**Richard H.J. Begent, M.D.**, *Head of Oncology, Ronald Raven Professor of Oncology, University College London, United Kingdom*

### 3:00 Visualization of Tumor Targeting at High Resolution

Solid tumors possess a spatially and temporally heterogeneous pathophysiology, which has a major impact on both the distribution and efficacy of systemically delivered therapies. The use of novel high-resolution microscopy, to investigate the effect of the tumor microenvironment on antibody-targeted therapies, will be discussed for both subcutaneous and liver metastatic models of colorectal cancer. This work illustrates the importance of studying intratumor antibody distribution for the optimization of therapies.

**R. Barbara Pedley, Ph.D.**, *Reader in Tumor Biology, UCL Cancer Institute, United Kingdom*

### 3:30 Vascular Targeting with Recombinant Antibody Derivatives: From the Bench to the Clinic

The formation of new blood vessels is a relatively rare event in the adult, but these structures can serve as excellent targets for the antibody-based delivery of therapeutic agents. Our laboratory, in collaboration with Luciano Zardi and with Philogen, has brought six vascular targeting antibody derivatives into clinical development programs.

**Dario Neri, Ph.D.**, *Professor, Department of Chemistry and Applied Biosciences, ETH Zürich, Switzerland*

### 4:00 Networking Refreshment Break

### 4:30 Array-Based Oncoproteomics using scFv Microarrays - A Tool for Clinical Diagnostics?

We have developed a high-performing, human antibody microarray technology platform, based on designed scFv antibody fragments. This microarray platform has now been applied in more than ten different clinical studies, including analysis of serum/plasma proteomes from patients suffering from e.g. metastatic breast carcinoma, glioblastoma multiforme, pancreatic carcinoma, gastric adenocarcinoma, chronic lymphocytic leukemia etc. Data demonstrating the accuracy and predictability of array-based proteomics in oncoproteomics will be discussed.

**Carl A.K. Borrebaeck, Ph.D.**, *Program Director, Department of Immunotechnology, Create Health - The Strategic Center for Translational Cancer Research, Lund University, Sweden*

### 5:00 Applications of rPEG to dAbs, scFvs and Diabodies

rPEG is Amunix' recombinant, unstructured amino acid polymer of 25-50kD that is genetically fused to proteins to increase their serum half-life. Whereas PEG is not biodegradable and accumulates to form vacuoles in kidney cells, rPEG is biodegradable. A benefit of rPEG fusions to eukaryotic proteins, including antibody fragments, is the increased solubility of the proteins in the cytoplasm, preventing inclusion body formation. By adding rPEG, we have been able to express a variety of antibody fragments in soluble, active form in the *E. coli* cytoplasm.

**Willem 'Pim' Stemmer, Ph.D.**, *Chief Executive Officer and Founder, Amunix Inc.*

### 5:30 scFv Derived by Nanoselection and their Application to Parkinson's Disease and Huntington's Disease

Protein misfolding and assembly into toxic aggregates is a shared feature in numerous neurodegenerative diseases including Parkinson's and Huntington's Diseases. By combining the diversity of surface display antibody libraries with the imaging capabilities of Atomic Force Microscopy, we developed biopanning protocols that enable isolation of antibody fragments to specific protein morphologies. The antibody fragments can be used either extracellularly or intracellularly to target specific toxic species involved in disease progression.

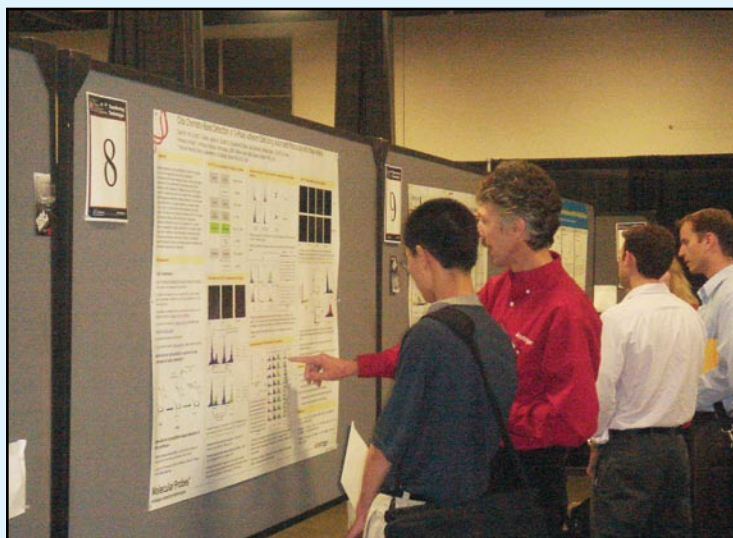
**Michael Sierks, Ph.D.**, *Professor, Chemical Engineering, Arizona State University*

### 6:00 Networking Cocktail Reception; Opening of Poster and Exhibit Hall



## Poster Presentations

(Abstract Deadline October 31, 2008)



The organizers of Antibody Engineering recognize the significant educational value in poster presentations. Any registered conference attendee may register to present a poster. The deadline to submit an abstract online, at the address below, is **October 31, 2008** to have the abstract be included in the conference materials. Poster abstracts and registrations received after **October 31, 2008** are subject to availability of an onsite poster board and will not be included in the conference materials. Full payment of conference registration and poster fees must also be received by this date for the abstract to be included in the conference materials and a poster board assignment to be made (see the registration page for details on the poster fee). The size of the poster board is 4'h x 8'w. Please note: Poster presentations may not be used as exhibit displays or for marketing purposes, and all posters are subject to approval by conference organizers. Only one poster presentation is allowed per registered attendee/author.

Poster abstracts should be submitted online at:

**[www.IBCLifeSciences.com/Antibodyeng](http://www.IBCLifeSciences.com/Antibodyeng)**

7:00 Registration, Networking Coffee

7:45 Announcements

### Session III: The Theory, Practice and Use of Libraries Based on Restricted Amino Acid Sets

#### 7:50 Chairperson's Opening Remarks

Andrew Bradbury, M.B., B.S., Ph.D., *Research Scientist, Los Alamos National Laboratories*

#### 8:00 The Antibody Combining Site and Tools to Link Antibody Sequence and Structure

We have analyzed characteristics of the 6 "complementarity determining regions" (CDRs) which encode antibody variability and specificity with regard to the general class of antigen with which they interact. These results may help guide antibody library generation. More recently we have developed a number of tools for working with antibody sequence and structure including a measure of "humanness", analysis of VH/VL packing and an integrated database of antibody sequence and structure known as AYSIS. These tools and their applications will be presented.

Andrew C.R. Martin, D.Phil., *Senior Lecturer in Bioinformatics, Institute of Structural and Molecular Biology, Division of Biosciences, University College London, United Kingdom*

#### 8:30 Defined-Sequence Libraries in Antibody Engineering

Our library-construction method relies on complex mixtures of defined-sequence oligonucleotides as the source of diversity. This allows the diversity at each position to be restricted to a defined subset of amino acids, with a particular probability of occurrence assigned to each amino acid. In addition, such libraries can incorporate higher-order design rules, such as diversity correlated between up to twenty adjacent amino-acid residues. This allows the user control over properties encoded by linear oligopeptide sequence.

Dasa Lipovsek, Ph.D., *Director of Protein Engineering, Codon Devices, Inc.*

#### 9:00 Slonomics – A Novel Technology for the Generation of Highly Designed Gene Libraries

We have developed a novel mutagenesis technology based on the iterative assembly of base triplets. This technology is especially suited to generate highly designed gene libraries for the use in e.g. antibody display experiments. The high degree of control over type, number and proportion of codons within variable regions and its impact on screening success will be demonstrated.

Jan Van den Brulle, Ph.D., *Head of Research and Development, Sloning BioTechnology GmbH, Germany*

9:30 Networking Refreshment Break, Exhibit and Poster Viewing

#### 10:15 Highly Functional Minimalist Antibodies

Highly functional antibodies can be designed with combining sites composed of just two amino acids (tyrosine and serine). In this minimalist background, we have explored fundamental aspects of molecular recognition and evolution by systematically replacing or adding to the binary code. We find that antigen recognition is simpler than previously believed and we can design simple, synthetic antibodies with properties beyond those of natural antibodies.

Sachdev Sidhu, Ph.D., *Associate Professor, University of Toronto, Canada*

#### 10:45 Minimalist Design of Synthetic Binding Proteins using Non-Antibody Scaffolds

Generating novel functions using simple scaffolds has become a major branch of protein engineering. Restricted diversity libraries of the fibronectin type III scaffold produce high-performance binding proteins, overcoming the combinatorial challenge. In these minimalist interfaces, tyrosines and conformational diversity play dominant roles in forming productive interactions. By expanding this minimalist approach we have developed "affinity clamps", a new class of synthetic binding proteins targeted to short peptide motifs.

Shohei Koide, Ph.D., *Associate Professor, Biochemistry & Molecular Biology, University of Chicago*

#### 11:15 The Path to Platinum: The Evolution of Human Combinatorial Antibody Libraries (HuCAL®)

Trinucleotides (TRIMs) have been used as core technology for diversification of CDRs in all HuCAL Libraries. TRIM synthesis guarantees a high quality and sequence diversity can be restricted to the set of amino acid found in nature. In HuCAL Gold® six CDRs have been diversified in up to 61 positions. The CDR design in HuCAL Platinum™, presented here the first time, was refined to obtain a higher number of functional CDR3 sequences.

Josef Prassler, Ph.D., *Associate Director, Research & Development, MorphoSys AG, Germany*

#### 11:45 Technology Workshops

##### Therapeutic Antibodies without Helper T Cell Epitopes



Data will be presented demonstrating enhancements in the *in vitro* detection of T cell epitopes within therapeutic antibodies. This enhanced method has been applied to screen lead therapeutic antibodies during preclinical development, and provides an assessment for the relative risk of immunogenicity. Furthermore, data will be presented in which a refinement of this process has been applied to enable the selection of fully human sequence segments that are devoid of T cell epitopes.

Frank J. Carr Ph.D., *Director for Biologics Research, Antitope, United Kingdom*

##### PER.C6® Cells: A Highly Efficient Production Platform for Antibodies



Yields of 8 g/L in fed-batch and 27 g/L using DSM's XD™ for IgGs and over 1.5 g/L in fed-batch for IgMs are now possible due to the ability to obtain stable clones producing 50 picograms of IgG per cell per day and 20 pcgs of IgM, reliably, using the PER.C6® cell line. The workshop will focus on key aspects of the technology and economic impact relative to current approaches in manufacturing of protein therapeutics.

Marco A. Cacciuto, Ph.D., *President & Chief Executive Officer, Percivia LLC*

##### Presentation Topic TBA



Speaker TBD, FortéBio

12:15 Networking Luncheon, Exhibit and Poster Viewing

1:45 **Technology Workshop**
**Balancing Power and Simplicity in Real Time, Label-Free Characterization/ Selection of Antibodies and Development of Biopharmaceuticals: The Added Value of Biosensors**


This presentation will discuss the applications of Attana's label-free, real time analysis technology to address the current market needs for high quality and cost-efficient analysis of molecular interactions. The presentation will also highlight different applications focusing on biopharmaceutical developments. How can biosensors provide added value?

**Johan Lindberg**, Vice President, Sales & Marketing, Attana AB, Sweden

1:45 **Technology Workshop**
**Development of MOR103, a GM-CSF Specific Human Antibody for the Treatment of Inflammatory Diseases Currently Tested in a Phase I Clinical Trial**


MOR103 targets GM-CSF, a pro-inflammatory cytokine implicated in the pathogenesis of several auto-immune diseases e.g. rheumatoid arthritis. Utilizing the modular design of the human combinatorial antibody library (HuCAL<sup>®</sup>) enabled antibody optimization via targeted CDR diversification. Preclinical data demonstrating the mode of action of MOR103 will be presented. Currently MOR103 is tested in a Phase I clinical trial to assess safety, tolerability and the pharmacokinetics of this fully human high affinity anti-GM-CSF HuCAL antibody.

**Stefan Steidl, Ph.D.**, Associate Director, MorphoSys AG, Germany

**Session IV: Are Non-Antibody Scaffolds Really any Better than Antibody Fragments?**
2:15 **Announcements and Chairperson's Opening Remarks**

**Ian M. Tomlinson, Ph.D.**, Vice President, GSK-Domantis Group, United Kingdom

2:30 **Immunogenicity Problems: A Paradigm Shift?**

Tools designed by expert immunoinformaticians have enabled the prediction of immunogenicity and the prospective identification of subjects who may be at increased risk of developing adverse immune responses. These same techniques can also be used to elucidate the dynamic balance between T effector and T regulatory cells in the development and treatment of autoimmune diseases. This presentation illustrates the use of these tools to predetermine immunogenicity. Techniques for salvaging immunogenic therapeutics are also addressed.

**Anne S. De Groot, M.D.**, Associate Professor of Pediatric Infectious Disease (adjunct), Brown University Medical School; Director, Institute for Immunology and Informatics, University of Rhode Island; Chief Executive Officer, EpiVax

3:00 **DARPinS, the Next Generation Protein Drugs**

DARPinS are a novel class of binding molecules combining the advantages of antibodies with the ones of small molecule drugs. The unreach high affinity target binding is combined with exceptional stability, cost effective production and low immunogenic potential. DARPinS have been validated in several different disease models. The DARPin scaffold allows for a whole range of format choices, allowing tailored drug design for improved therapies. An example of how this can translate into patient benefit will be discussed.

**Christian Zahnd, Ph.D.**, Chief Executive Officer, Molecular Partners, Switzerland

3:30 **Single Variable Antibody Domains from Camelids – Pros and Cons of Being Camelid**

Camelids have unique homodimeric heavy chain antibodies with an antigen-binding site comprised in one single domain, known as Nanobody. After a short immunization, high affinity, antigen-specific Nbs are retrieved by various display and selection techniques. The stable, soluble and strict monomeric Nbs are easily humanized or tailored into pluripotent constructs, employed as research tool in immuno-precipitations, to localize antigen in living cells, or to diagnose and treat infections and diseases.

**Serge Muyldermans, Ph.D.**, VIB Department of Molecular and Cellular Interactions, Vrije University, Belgium

4:00 **Networking Refreshment Break, Exhibit and Poster Viewing**4:45 **Human Domain Antibodies: From Selection to Innovative Products**

Human Domain Antibodies (dAbs) offer innovative therapeutic opportunities such as pulmonary delivery and dual targeting thanks to their thermodynamic stability, intrinsic solubility and tolerance to engineering for potency and formatting. The first dAb products are now in the clinic and several late stage preclinical assets are following close behind. Case studies will illustrate how desired functionality and manufacturability have been achieved by process optimization right from phage library selection.

**Laurent S. Jespers, Ph.D.**, Director of Protein Engineering, Domantis Limited, United Kingdom

5:15 **Anticalins<sup>®</sup>, a Novel Class of Binding Proteins, and their use as Therapeutics**

Anticalins<sup>®</sup>, which are derived from human lipocalins, are small 20kDa proteins with highly selective binding properties. The use of Anticalins has already been validated *in vivo* for oncology, inflammation, ophthalmology and molecular imaging. Recent data for the clinical candidate PRS-050 (VEGF antagonist) will be presented. Moreover, unique features such as dual targeting and pulmonary delivery that come along with the compact structure, intrinsic stability and broad formulation flexibility of Anticalins will also be discussed.

**Evert J. J. Kueppers**, Chief Executive Officer, Pieris AG, Germany

5:45 **Adnectins: Realizing the Promise of a Novel Class of Targeted Biologics**

Adnectins, a novel, proprietary class of targeted biologics, are derived from a human, extracellular protein, fibronectin. Adnectin-based products offer potential advantages compared to traditional biologics, including speed of discovery, ease of manufacturing, and the ability to create multi-functional targeted antagonists and agonists. CT-322, an Adnectin inhibitor of VEGFR-2, had potent activity in a Phase I study, based on changes in biological and pharmacodynamic markers. Data for the next generation of Adnectins will also be presented.

**Eric Furfine, Ph.D.**, Senior Vice President, Research and Preclinical Development, Adnexus

6:15 **Networking Cocktail Reception, Exhibit and Poster Viewing**

7:30 Registration, Networking Coffee

### Session V: Intrabodies Revisited

#### 8:00 Announcements and Chairperson's Opening Remarks

**Andreas Plückthun, Ph.D.**, Professor of Biochemistry, Department of Biochemistry, University of Zürich, Switzerland

#### 8:15 Interfering with RAS-Effector Protein Interactions Inside Cells

RAS mutations occur in many human cancers but attempts to develop drugs blocking protein interactions between RAS and effectors have been ineffective. We have developed methods, including intracellular antibody capture (IAC), to select single domain interfering antibodies that block protein-protein interactions. This is exemplified with interfering antibodies that bind activated RAS, prevent it binding its effectors and inhibiting tumourigenesis in mouse models. Our findings have implications for drugging "undruggable" protein-protein interactions in disease.

**Terence H. Rabbitts Ph.D.**, FRS, FMedSci, Director, Leeds Institute of Molecular Medicine, United Kingdom

#### 8:45 Protein Silencing: Engineering Intrabodies for Targeted Protein Degradation

Strategies to confer protein neutralizing properties to Intrabodies include 3-SPLINT, a technology for the selection of antibody domains that are intrinsically endowed with the ability to interfere with target protein-protein interaction domains, and a protein silencing switch made by engineering ligand-induced proteasome-targeting intrabodies. Silencing intrabodies are able to rapidly and effectively redirect intracellular target proteins for degradation in a catalytic fashion. Applications of intrabodies against Alzheimer's amyloid A $\beta$  oligomers are presented.

**Antonino Cattaneo, Ph.D.**, Professor of Biophysics, European Brain Research Institute and International School for Advanced Studies, Italy

#### 9:15 Facts and Fairy Tales about Tat-Mediated Uptake of Peptides, Proteins and Antibodies

During the last decade, the potential of cell-penetrating peptides (CPPs) for cellular drug delivery has been highlighted by the discovery of the Tat- and the Antennapedia-derived peptides. These CPPs are actually very efficient in delivering their "cargo" molecules into various cell types. "Cargoes" include peptides, proteins, antibodies, oligonucleotides, drugs, or even bigger entities such as liposomes or nanoparticles. In this presentation, the "pros" and "cons" of using CPPs as a tool for drug delivery will be discussed.

**Eric Vives, Ph.D.**, Assistant Professor, University of Montpellier, France

9:45 Networking Refreshment Break, Exhibit and Poster Viewing

#### 10:30 Small Molecule Mimics of an Alpha-Helix for Efficient Transport of Proteins into Cells

We have designed and synthesized small-molecule mimics of an alpha-helical peptide protein transduction domain (a). These small-molecule carriers, which we termed SMoCs, are easily coupled to biomolecules, and efficiently deliver dye molecules and recombinant proteins into a variety of cell types. As an example of a protein cargo, we applied this new technology to the internalization of the DNA replication licensing repressor geminin, *in vitro*, providing evidence that extracellularly delivered SMoC-geminin can have an anti-proliferative effect on human cancer cells.

**David L. Selwood, BSc CSci FRSC CChem**, Head of Biological Chemistry, Wolfson Institute for Biomedical Research, University College London, United Kingdom

#### 11:00 The Human TOPONOME Project: Translating the Cellular Protein Network Code into Efficient Therapies

A technology termed MELC/TIS enables researchers for the first time to address the hierarchical properties of protein networks directly in any cell or tissue section by colocalizing hundreds of proteins simultaneously using large tag libraries, e.g. antibodies (Nat. Biotechnology 24, 1270-1278, 2006). Clinical proofs of concept lay the ground for a human toponome project deciphering the protein network code (toponome) of human diseases for immediate pharmacological and clinical applications.

**Walter Schubert, M.D.**, Professor for Toponomics, International Faculty, Max Planck-CAS Partner Institute for Computational Biology, China; Head Molecular Pattern Recognition Research Group, University of Magdeburg, Germany

#### 11:30 DARPins Inside

Designed Ankyrin Repeat Proteins (DARPins), besides having shown excellent promise for *in vivo* applications on extracellular targets, can also be used as a tool to study cytoplasmic targets. Since all members of the library are stable to the reducing environment and fold well without aggregation even as fusion proteins, the full diversity can be exploited. Progress on observing and inhibiting a variety of intracellular events will be discussed.

**Andreas Plückthun, Ph.D.**, Professor of Biochemistry, Department of Biochemistry, University of Zürich, Switzerland

#### 12:00 Technology Workshop

##### Clinical Trials using Potelligent® Mabs



Depletion of the target cell population expressing a specific antigen is one of the therapeutic concepts of antibody drugs. Potelligent® technology enhances the ADCC activity of therapeutic antibodies, which is the key mechanism of action of those depleting antibodies. In this presentation, clinical studies using Potelligent® antibodies in the oncology and inflammatory areas will be discussed.

**Masamichi Koike, Ph.D.**, President and Chief Executive Officer, BioWa, Inc.

12:30 Networking Luncheon; Last Chance for Exhibit and Poster Viewing

### Session VI: Novel Antibody Targets and Applications

#### 2:00 Announcements and Chairperson's Opening Remarks

**Dennis R. Burton, Ph.D.**, Professor, Immunology Department, The Scripps Research Institute

#### 2:15 Bacterial Quorum Sensing as a Target for Anti-Infective immunopharmacotherapy

Quorum sensing (QS) is the process through which bacteria communicate utilizing small diffusible molecules termed autoinducers. It has been demonstrated that QS controls a plethora of microbial processes including the expression of virulence factors. This lecture will detail an immunopharmacotherapeutic strategy for the prevention or treatment of infections in which QS signaling contributes to bacterial pathogenesis.

**Kim D. Janda, Ph.D.**, Professor, Departments of Chemistry and Immunology, Ely R. Callaway, Jr. Chair in Chemistry, Director, Worm Institute of Research and Medicine (WIRM), The Scripps Research Institute

2:45 **Molecular Mechanisms of the Anti-Inflammatory Activity Of IVIG**

Monomeric IgG, when administered at very high concentrations, is a well-established therapeutic for the treatment of autoimmune inflammatory disorders. A fully recombinant preparation was developed in which a 2,6 sialylated IgG1 Fc can recapitulate the biological activities of IVIG with a potency 30 fold greater than IVIG. The consequences of 2,6 sialylated Fc binding to this lectin initiates an anti-inflammatory cascade, ultimately resulting in enhanced expression of the inhibitory Fc receptor, FcRIIB, on effector macrophages.

**Jeffrey Ravetch, Ph.D.**, Professor, Laboratory of Molecular Genetics and Immunology, Rockefeller University

3:15 **New Approaches to Discovery of Effective Prophylactic and Therapeutic Antibodies to Influenza, Including Avian Viruses**

New ways to protect groups most vulnerable to influenza are needed, since Oseltamivir resistance is on the rise and influenza vaccines have been shown to be less effective in the elderly. There is preliminary and anecdotal evidence that immunoglobulins from survivors of the 1918 H1N1 pandemic and from individuals surviving H5N1 avian influenza may be therapeutically effective. We report the discovery of influenza virus neutralizing human monoclonal antibodies effective against a broad range of avian and human influenza strains.

**Jaap Goudsmit, M.D., Ph.D.**, Chief Scientific Officer, Member of the Management Board, Crucell NV, The Netherlands

3:45 *Networking Refreshment Break*4:15 **Neutralizing Antibody Solutions from H5N1 Avian Influenza Survivor Combinatorial Antibody Libraries**

We have generated combinatorial antibody libraries from the bone marrow of convalescent H5N1 Avian influenza survivors that have yielded >300 unique antibodies against H5N1 viral antigens. Amongst these antibodies, we have identified several broadly neutralizing, anti-hemagglutinin antibodies for use as passive immunization against H5N1 viral infection. Remarkably three such antibodies neutralize a broad range of present and past H5 clades, as well as several relevant H1 subtype influenza viruses.

**Ramesh R. Bhatt, Ph.D.**, Vice President, Research, Sea Lane Biotechnologies

4:45 **Domain Exchanged Antibodies to Glycans**

Although antibody responses to glycans, such as those present on the surface of invading microorganisms, are well documented, the quality and quantity of the antibodies ordinarily elicited clearly identify carbohydrates as a hypoimmunogenic antigenic class. To overcome this limitation, we are using domain-exchanged antibodies, in which the VH domains of the molecule are swapped, as a unique structural template for generation of high affinity antibodies binding specifically to glycan targets.

**Anthony Williamson, Ph.D.**, President and Chief Executive Officer, Calmune

5:15 **A Unique Class of Protective Human Anti-M2 mAbs for Pandemic Influenza**

M2, is a highly conserved, virally encoded transmembrane protein present on the surface of influenza A virus and infected cells. We have isolated mAbs directly from human B cells that recognize an unanticipated, conformational epitope within M2 using a novel antibody discovery platform. This unique class of human anti-M2 mAbs could be useful as therapeutic agents for protection from and treatment for pandemic influenza, and also as a tool for the design of a universal influenza vaccine.

**Matthew Moyle, Ph.D.**, Senior Vice President, Research and Development, Chief Scientific Officer, Spaltudaq Corporation

5:45 *Close of Session*7:30 *Networking Coffee***Session VII: Antibodies in a Complex Environment: Target Selection in Relation to Efficacy**8:05 **Announcements and Chairperson's Opening Remarks**

**Richard H.J. Begent, M.D.**, Head of Oncology, Ronald Raven Professor of Oncology, University College London, United Kingdom

8:15 **B7-H1 Pathway as a Therapeutic Target of Antibody in Cancer and Autoimmune Diseases**

Upon engaging its receptor(s) on T and B cells, B7-H1 induces T cell to undergo apoptosis, exhaustion and anergy, therefore, downregulating immune and inflammatory responses. In addition to be a ligand, tumor-associated B7-H1 could also serve as a receptor to receive signal from PD-1, one of B7-H1 receptor on T and B cells. Antibody blockade of B7-H1 or its receptor represents a new approach to enhance immune responses against cancer and viral infection.

**Lieping Chen, M.D., Ph.D.**, Professor, Dermatology, Oncology and Immunology, Johns Hopkins University School of Medicine

8:45 **Blocking Inhibitory Self-Recognition to Promote ADCC**

To improve the magnitude of ADCC, we have previously manipulated antibody structures and cytokine milieu. Here we show that the ADCC-based effector cell responses can be amplified by blocking inhibitory self-recognition in a human model, applying an autologous system in which physiologic checkpoints are in place. This method provides an alternative approach to potentiate the therapeutic benefit of antitumor antibodies that mediate ADCC.

**Louis M. Weiner, M.D.**, Director, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center

9:15 **Systems Optimization of ErbB-Targeted Therapeutics: Development of an Anti-ErbB3 Monoclonal Antibody**

Computational biology is improving our understanding of complex biological systems. Using very large biological datasets of cell signaling, we have constructed detailed, mechanistic models. These may be used to predict network responses to targeted therapeutics such as monoclonal antibodies and small molecule inhibitors. Using the ErbB signaling network as an example, we will present how simulation proposed MM-121, a monoclonal anti-ErbB3 antibody, as a potentially superior approach current therapies.

**Ulrik B. Nielsen, Ph.D.**, Senior Vice President, Research, Merrimack Pharmaceuticals

9:45 *Networking Refreshment Break*10:15 **Adapting Antibodies According to Target Diversity in Viral Diseases and Cancer**

Antigenic variability of circulating viral strains and neutralization escape have been longstanding barriers to commercial development of human(ized) mAbs for prophylaxis and treatment of viral infections. Similar evasion mechanism(s) can exist with human cancers where mAb refractory disease can arise due to downregulation and/or modulation of target epitopes. Our studies on different types of combination immunotherapies will be discussed with emphasis on target diseases, epitope selection, escape mechanisms, and mAb based strategies to prevent escape.

**Wayne A. Marasco, M.D., Ph.D.**, Associate Professor of Medicine, Department of Cancer Immunology and AIDS, Dana-Farber Cancer Institute; Department of Medicine, Harvard Medical School, Scientific Director, National Foundation for Cancer Research (NFCR) – Center for Therapeutic Antibody Engineering (CTAE)

### 10:45 **Anti-Human Transferrin Receptor Avidin Fusion Protein: A Molecule Capable of a Two-Pronged Attack Against Malignant Cells through Toxin Delivery and Direct Induction of Apoptosis**

We have demonstrated that fusing avidin to a mouse/human chimeric IgG3 specific for the human transferrin receptor results in a novel molecule (anti-hTfR IgG3-Av) with intrinsic pro-apoptotic activity against hematopoietic malignant cells. In addition, conjugation of anti-hTfR IgG3-Av with biotinylated toxins significantly enhances the cytotoxic effect of the fusion protein and overcomes resistance. Therefore, the anti-hTfR IgG3-Av is a molecule capable of a two-pronged attack against malignant cells through toxin delivery and direct induction of apoptosis.

**Manuel L. Penichet, M.D., Ph.D.**, Assistant Professor, Assistant Professor of Surgery and Immunology, Division of Surgical Oncology, University of California, Los Angeles

### 11:15 **An Integrated System for Tumor Detection and Targeted Drug Therapy using ADEPT: Preclinical, Clinical Testing and Mathematical Modeling**

Surgery is the most common treatment for cancers. However, the threat of unrecognized occult disease remains a major challenge for the surgeons. For patients with unresectable and advanced cancer, the standard chemotherapy yields poor response. We intend to develop a system using ADEPT for intraoperative real-time detection of occult tumors and abnormal lymph nodes, as well as to provide a therapeutic regimen for unresectable and advanced cancers in preclinical models, clinical patients, and mathematical modeling.

**Duxin Sun, Ph.D.**, Associate Professor, Department of Pharmaceutical Sciences, College of Pharmacy, University of Michigan

11:45 *Lunch on Your Own*

1:15 *Announcements*

## Session VIII: Mechanism of Antibody Action Revisited

### 1:20 **Chairperson's Opening Remarks**

**James D. Marks M.D., Ph.D.**, Department of Anesthesia and Pharmaceutical Chemistry, Member, Comprehensive Cancer Center, University of California, San Francisco

### 1:30 **How Antibody Combinations Synergize to Potently Neutralize Botulinum Neurotoxins**

We have been generating antibodies to botulinum neurotoxin types A, B, and E (BoNTs) as treatments for botulism. Single antibodies do not neutralize BoNTs with the required potency, however combining antibodies leads to extremely potent BoNT neutralization. Using molecular evolution, we have determined the impact of epitope, affinity, and clearance mechanisms on BoNT neutralization for single mAbs and mAb combinations. The results identify the major mechanisms by which antibodies synergize to neutralize toxin and provide a path for development of highly potent recombinant BoNT antitoxin.

**James D. Marks M.D., Ph.D.**, Professor of Anesthesia and Pharmaceutical Chemistry, University of California, San Francisco

### 2:00 **Antibody Mixture Regresses Tumors by a Novel Mechanism**

Data will be presented on the potent anti-tumor effect exerted by antibody mixture targeting a tumor-associated antigen. *In vitro* and *in vivo* experiments have shown a unique mechanism of action leading to sustained growth inhibition of cancer cells and potent efficacy in an aggressive xenograft tumor model. Also, data has been obtained from a tolerability study in Cynomolgus monkeys showing that the antibody mixture is well tolerated.

**John Haurum M.D.**, Chief Scientific Officer, Symphogen A/S, Denmark

### 2:30 **Selection of Anti-CD22 Antibodies Based on Physiology and Epitope**

A panel of anti-CD22 mAbs were developed and tested. Anti-CD22 mAbs that bind the two NH<sub>2</sub>-terminal immunoglobulin domains of CD22 and specifically block the interaction of CD22 with its ligand were identified. Our studies have determined that the epitope bound by an anti-CD22 mAb, the interval between doses, target receptor resurfacing, and initial tumor size are critical factors that can predict preclinical efficacy.

**Joseph M. Tuscano, M.D.**, Associate Professor of Medicine, University of California Davis Cancer Center

3:00 *Networking Refreshment Break*

### 3:15 **k-ras Mutations and Response to Cetuximab Treatment**

This abstract was not available at the time of printing the brochure. For up to date program information, please visit [www.IBCLifeSciences.com/Antibodyeng](http://www.IBCLifeSciences.com/Antibodyeng)

**David J. Mauro, M.D., Ph.D.**, Bristol Myers Squibb

### 3:45 **Fc- and Fcy Receptor-Dependent Mechanisms in Cell-Targeted Monoclonal Antibody Immunotherapy**

Evidence supports a role for Fc interactions with low-affinity Fc receptors (FcRs) in the mechanism of action of cell-targeted therapeutic monoclonal antibodies (mAbs). The function of both activating (CD16, CD32A) and inhibitory (CD32B) FcRs can be exploited to modify antibody potency. We have developed strategies that modulate Fc interactions with these receptors or selectively target individual receptors; results from these FcR-targeted interventions are presented that address the role of these receptors in mAb function *in vitro* and *in vivo*.

**Ezio Bonvini, M.D.**, Senior Vice President, Research, MacroGenics, Inc.

### 4:15 **Enhancement of Effector Function for Small Modular ImmunoPharmaceutical (SMIP™) Compounds and Other Protein Therapeutics**

SMIP™ proteins are single-chain polypeptides manufactured as dimeric products that are approximately one-half the size of monoclonal antibodies. Three SMIP candidates are currently in clinical trials and, as a class, are capable of utilizing effector functions. Given the association between clinical response and ADCC activity, we have developed a technology that allows for significant increases in ADCC activity irrespective of CD16 allelotype via addition of small molecule inhibitors of glycosylation during the bioreactor production process. This technology is applicable to SMIPs and other protein therapeutics.

**Kendall M. Mohler, Ph.D.**, Senior Vice President, Research & Development, Trubion Pharmaceuticals

4:45 *Close of Meeting*

# Antibody Therapeutics

*Advancing Therapeutic Antibodies; Tracking Preclinical and Clinical Development; the Antibody Business Climate; Intellectual Property Updates*

As a registered delegate for the Antibody Engineering conference, you will also have access to the sessions and materials of the 6th Annual Antibody Therapeutics conference. You may move freely among the sessions of both events and **customize your conference experience** to meet the needs of you and your organization.

Antibody Therapeutics provides a focused look at the preclinical and clinical development of antibody-based drug products. At this year's meeting, you will hear **updates of preclinical and clinical stage programs**, review the current state of the antibody therapeutics market and learn about trends in IP law that could impact your development candidates.

To register or for up-to-date Antibody Therapeutics information visit [www.IBCLifeSciences.com/Antibodyther](http://www.IBCLifeSciences.com/Antibodyther)

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## Main Conference

**Tuesday, December 9, 2008**

7:00 *Registration, Networking Coffee*

7:45 *Announcements*

### Session I: Preclinical Development of Antibody Therapeutics

#### 7:50 **Chairperson's Opening Remarks**

**Rathin C. Das, Ph.D.,** *Chief Business Officer, President,*  
**Affitech AS/Affitech USA, Inc.**

#### 8:00 **Challenges in Preclinical Development of Monoclonal Antibodies**

One of the challenges facing antibody development in oncology is the reactivity of the antibody to target antigens in preclinical models. This presentation focuses on the advantages and disadvantages of different *in vitro* and *in vivo* model systems for screening antibodies; using transgenic animals and surrogate antibodies to test antibodies that lack murine cross-reactivity against the target antigen; and the utility of these model systems to understand the mechanism of action as well as pharmacodynamic readouts.

**Steve Coats, Ph.D.,** *Director of Oncology Research and Development,*  
**MedImmune, Inc.**

#### 8:30 **Stability-engineered IgG-like Tetravalent Antibody for Inducing Receptor-mediated Death in Leukemia Cells**

We have developed technology for engineering stable single-chain Fv domains that serve as building blocks for constructing IgG-like bispecific and tetravalent antibodies. A stability-engineered tetravalent antibody targeting receptors expressed on the surface of leukemia cells was developed as a potentially more potent inducer of tumor cell death. Data will be presented characterizing the stability-engineered tetravalent antibodies as well as results from studies examining the effects on tumor cell apoptosis.

**Scott M. Glaser, Ph.D.,** *Director, Molecular Engineering, Biogen Idec, Inc.*

#### 9:00 **Preclinical Development of the Vascular Targeting Antibody, 1N11**

Phosphatidylserine (PS) becomes exposed on tumor blood vessels in response to stress conditions in the tumor microenvironment. Anti-PS antibodies have been developed that recruit immune cells that destroy tumor vasculature. The antibodies also enhance anti-tumor immunity by blocking the immunosuppressive action of PS. A chimeric anti-PS antibody, baviximab, is being used in combination with chemotherapy to treat patients with metastatic breast cancer in Phase II trials. A fully human anti-PS antibody, 1N11, has been developed for further clinical trials.

**Philip E. Thorpe, Ph.D.,** *Serena S. Simmons Distinguished Chair,*  
**University of Texas Southwestern Medical Center**

9:30 *Networking Refreshment Break, Exhibit and Poster Viewing*

### 10:15 **Fc-Engineering Increases the *In vitro* and *In vivo* Anti-tumor Activity of an Anti-CD19 Antibody**

CD19 is an excellent target for antibody-based therapies of B cell neoplasms due to its pan-B cell expression profile. To develop a highly cytotoxic anti-CD19 antibody (XmAb<sup>®</sup>5574) we employed protein engineering and increased the affinity of the Fc domain for Fc(gamma)Rs on immune effector cells. XmAb5574 displayed dramatically increased cytotoxic activity relative to the native unmodified analog *in vivo* and *in vitro* and therefore warrants further clinical evaluation.

**Eugene Zhukovsky, Ph.D.**, Associate Director, Protein Chemistry/Research, Xencor

### 10:45 **Preclinical Development of Antibody Combinations and Bispecific Antibodies for Anticancer Therapy**

Combinations of antitumor antibodies may provide greater efficacy than single antibody without adding significant toxicities. However, the research and development costs of antibodies pose a significant barrier to the use of antibody combinations. An emerging alternative is the use of dual-targeting bispecific antibodies (BsAb) that target simultaneously two tumor-associated antigens, thus providing a means of delivering two therapeutic moieties in one molecule. The rationales and biology of developing antibody combination and BsAb therapies will be discussed.

**Zhenping Zhu, M.D., Ph.D.**, Vice President, Antibody Technology and Immunology, ImClone Systems Incorporated

### 11:15 **Blinatumomab, a CD19-Specific Antibody Engaging T Cells for Treatment of Lymphoma**

BiTE is a novel antibody format capable of teaching conventional antibodies to recruit cytotoxic T cells, the most potent immune effector cells in the organism. With CD19/CD3-bispecific antibody blinatumomab, we have reached clinical proof of concept. Treatment of lymphoma patients with doses as low as 0.06 mg/square meter/day resulted in regression of tumors, and clearance of infiltrated organs, spleen and peripheral blood from target cells.

**Patrick A. Baeuerle, Ph.D.**, Chief Scientific Officer, Micromet Inc.

### 11:45 **Technology Workshops**

#### **Therapeutic Antibodies Without Helper T Cell Epitopes**



Data will be presented demonstrating enhancements in the *in vitro* detection of T cell epitopes within therapeutic antibodies. This enhanced method has been applied to screen lead therapeutic antibodies during preclinical development, and provides an assessment for the relative risk of immunogenicity. Furthermore, data will be presented in which a refinement of this process has been applied to enable the selection of fully human sequence segments that are devoid of T cell epitopes.

**Frank J. Carr Ph.D.**, Director for Biologics Research, Antitope, United Kingdom

#### **PER.C6<sup>®</sup> Cells: A Highly Efficient Production Platform for Antibodies**



Yields of 8 g/L in fed-batch and 27 g/L using DSM's XD<sup>™</sup> for IgGs and over 1.5 g/L in fed-batch for IgMs are now possible due to the ability to obtain stable clones producing 50 picograms of IgG per cell per day and 20 pcds of IgM, reliably, using the PER.C6<sup>®</sup> cell line. The workshop will focus on key aspects of the technology and economic impact relative to current approaches in manufacturing of protein therapeutics.

**Marco A. Cacciuttolo, Ph.D.**, President & Chief Executive Officer, Percivia LLC

#### **Presentation Topic TBA**



**Speaker TBD, FortéBio**

### 12:15 *Networking Luncheon, Exhibit and Poster Viewing*

### 1:45 **Technology Workshops**

#### **Balancing Power and Simplicity in Real Time, Label-Free Characterization/ Selection of Antibodies and Development of Biopharmaceuticals: The Added Value of Biosensors**



This presentation will discuss the applications of Attana's label-free, real time analysis technology to address the current market needs for high quality and cost-efficient analysis of molecular interactions. The presentation will also highlight different applications focusing on biopharmaceutical developments. How can biosensors provide added value?

**Johan Lindberg, Vice President, Sales & Marketing, Attana AB, Sweden**

#### **Development of MOR103, a GM-CSF Specific Human Antibody for the Treatment of Inflammatory Diseases Currently Tested in a Phase I Clinical Trial**



MOR103 targets GM-CSF, a pro-inflammatory cytokine implicated in the pathogenesis of several auto-immune diseases e.g. rheumatoid arthritis. Utilizing the modular design of the human combinatorial antibody library (HuCAL<sup>®</sup>) enabled antibody optimization via targeted CDR diversification. Preclinical data demonstrating the mode of action of MOR103 will be presented. Currently MOR103 is tested in a Phase I clinical trial to assess safety, tolerability and the pharmacokinetics of this fully human high affinity anti-GM-CSF HuCAL antibody.

**Stefan Steidl, Ph.D.**, Associate Director, MorphoSys AG, Germany



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## Session II: Clinical Development of Cancer Therapeutics (1)

### 2:15 Announcements and Chairperson's Opening Remarks

**Nils Lonberg, Ph.D.**, Senior Vice President and Scientific Director, Medarex Inc.

### Keynote Presentation

#### 2:20 Monoclonal Antibodies in Cancer Therapy: 30 Years of Progress

Hybridoma and recombinant DNA technologies and identification of key ligand-receptor-signal transduction pathways have led to several therapeutic monoclonal antibody products. In the past decade, nine have received regulatory approval for cancer therapy, including six unconjugated, one immunotoxin and two radiolabeled antibody products. They constructs are: one fully human, four humanized, two chimeric, and two murine. These products are now part of standard treatment of a variety of malignancies, especially in combination with chemotherapy.

**Robert O. Dillman, M.D.**, Medical & Scientific Director, Grace E. Hoag Director of Cancer Care, Hoag Cancer Center, Clinical Professor of Medicine, University of California, Irvine

#### 3:00 BMS-663513, a Fully Human Anti-CD137 Agonist MAb: Results from the First-in-Human Study

CD137 is a member of the TNFR superfamily and functions as a costimulatory molecule. In mouse tumor models, BMS-469492 (a mouse agonist anti-CD137 MAb) produced anti-tumor immune responses that led to tumor eradication. BMS-663513 is a fully human anti-CD137 agonist MAb. In preclinical studies, BMS-663513 provided costimulation to CD8+ and CD4+ T-cells, leading to enhanced IFN $\gamma$  production, cytolytic activity, and increased T-cell survival. Results from the first-in-human Phase 1 study are presented.

**David M. Feltquate, M.D., Ph.D.**, Director, Oncology Global Clinical Research, Research and Development, Bristol-Myers Squibb Co.

#### 3:30 Safety and Activity of MDX-1106 (ONO-4538), an Anti-PD-1 Monoclonal Antibody, in Patients Refractory Malignancies or Chronic Viral Infections

MDX-1106 is a fully human IgG4 (S228P) MAb to PD-1 that blocks engagement of this receptor by its ligands, and may promote anti-tumor and anti-viral immune responses. A Phase 1 study of MDX-1106 in patients with various malignancies has shown the antibody to be well tolerated, and provided early evidence of anti-tumor activity. An update of the Phase 1 study data and progress in new studies will be presented.

**Israel Lowy, M.D., Ph.D.**, Senior Director Clinical Science/Infectious Diseases, Medarex, Inc.

4:00 Networking Refreshment Break, Exhibit and Poster Viewing

#### 4:45 GA101: A 3rd Generation Glycoengineered CD20 Antibody with Superior Direct Cell Death Induction and Increased ADCC

GA101 is a humanized, glycoengineered type II CD20 antibody. Due to its type II mode of CD20 binding it has strong direct cell death induction compared to classical type I CD20 antibodies, a property enhanced through an engineered elbow hinge. The glycoengineered Fc region binds with high affinity to Fc $\gamma$ RIII on immune effector cells leading to increased ADCC. It has demonstrated outstanding efficacy in lymphoma xenograft models and in tissue B-cell depletion in preclinical models.

**Pablo Umaña, Ph.D.**, Head of Research, Glycart Biotechnology AG (Roche Group), Switzerland

#### 5:15 Preclinical Properties and Clinical Status of PSMA ADC, an Auristatin-Conjugated, Fully Human Monoclonal Antibody to Prostate-Specific Membrane Antigen

Prostate-specific membrane antigen (PSMA) is expressed abundantly on prostate carcinomas and the neovasculature of other solid tumors, and it has limited expression on normal, non-prostatic tissues. PSMA ADC comprises a fully human monoclonal antibody that binds PSMA and is linked to an antimetabolic agent, monomethylauristatin E (MMAE). PSMA ADC potently and selectively eliminated PSMA-expressing tumors in preclinical studies and is expected to next enter phase 1 testing in metastatic prostate cancer.

**William C. Olson, Ph.D.**, Vice President, Research and Development, Progenics Pharmaceuticals, Inc..

#### 5:45 SGN-35: Development of a Novel Antibody-Drug Conjugate Targeting CD30

SGN-35 is an antibody-drug conjugate (ADC) that specifically binds CD30 and delivers a potent antimetabolic drug, MMAE. A phase 1 clinical trial was conducted to test the safety, PK, and antitumor activity of SGN-35, administered every 3 weeks, in patients with relapsed and refractory CD30+ tumors (Hodgkin lymphoma and ALCL). Partial and complete responses have been observed at doses as low as 0.6 mg/kg and 1.2 mg/kg, respectively. Updated data will be presented.

**Jonathan G. Drachman, M.D.**, Vice President, Early Clinical Development, Seattle Genetics

6:15 Networking Cocktail Reception, Exhibit and Poster Viewing



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7:30 Registration, Networking Coffee

### Session III: Clinical Development of Cancer Therapeutics (2)

#### 8:00 Announcements and Chairperson's Opening Remarks

**Benjamin P. Chen, Ph.D.,** *Managing Director, Burrill & Company*

#### 8:15 Development of Mapatumumab, a Fully Human Agonistic Monoclonal Antibody which Targets and Activates the Tumor Necrosis Factor Apoptosis-Inducing Ligand (TRAIL) Receptor-1 – An Update

Mapatumumab is a fully human monoclonal antibody that targets and activates the TRAIL receptor-1. Pre-clinical experiments demonstrated that mapatumumab binds specifically to TRAIL-R1, efficiently induces apoptosis as a single-agent or in combination in TRAIL-R1 expressing human tumor cell lines, and can induce regressions in xenograft models of human tumors. The administration of mapatumumab has been very well tolerated as a single-agent and in combination with full-dose chemotherapy. Mapatumumab is currently being studied in randomized Phase 2 studies.

**Gilles Gallant, B.Pharm. Ph.D.,** *Vice President, Clinical Oncology, Human Genome Sciences, Inc.*

#### 8:45 Anaphylactic Reactions to Cetuximab in Patients with IgE antibodies Specific for Galactose alpha 1,3 Galactose

Investigation of anaphylactic reactions to the monoclonal antibody cetuximab demonstrated that they were due to pre-existing IgE antibodies to the glycosylation on the antibody. The results challenge the existing view that the glycosylation of recombinant molecules was unlikely to induce reactions. In addition the sugar concerned raises many questions about the reasons why the antibodies are common in this area and also about whether there are other disease associations with these antibodies.

**Thomas A.E. Platts-Mills, M.D., Ph.D.,** *Head Asthma and Allergic Disease, University of Virginia*

#### 9:15 Mechanisms of Therapeutic Antibodies Against EGF Receptor

Zalutumumab (HuMax-EGFr) is a human IgG1 antibody blocking the activation of the Epidermal Growth Factor receptor (EGFr) and efficiently recruiting effector cells for antibody-dependent cell-mediated cytotoxicity (ADCC). We investigated the interaction between zalutumumab and EGFr on cells, Zalutumumab was found to inhibit receptor activation by spatial mechanisms which efficiently prevented both ligand binding as well as receptor dimerization. Novel insights into the mechanism and role of antibody-mediated effector function in tumor cell killing will be discussed.

**Paul W.H.I. Parren, Ph.D.,** *Senior Vice President Research and Preclinical Development, Genmab, The Netherlands*

#### 9:45 Networking Refreshment Break, Exhibit and Poster Viewing

### Keynote Presentation

#### 10:30 Therapeutic Antibody Sector Remains Upbeat in Wake of Market Turmoil!

The therapeutic antibody sector's report card for the first half of the year continue to contain good grades for its performance on the capital markets, and for partnering and venture capital deal making, despite a very tough financial market. This Keynote will review the 2008 performance of the overall biotech industry and, in greater detail, the therapeutic antibody sector. We will assess the performance of the antibody sector in the context of the life sciences industry as a whole.

**Benjamin P. Chen, Ph.D.,** *Managing Director, Burrill & Company*

#### 11:00 Panel Discussion

#### Intellectual Property Issues in Antibody Development

The field of antibody therapeutics is evolving at an ever-increasing pace. So too are the legal issues facing companies and research institutions seeking to protect, enforce and/or leverage their proprietary antibody technologies. The strategies used to protect the pioneering antibody technologies of yesterday are not necessarily applicable to today's technologies. Companies must "stay ahead of the curve" by adapting their strategies to keep up with the ever changing legal and technological landscape. Our panel of experienced in-house IP counsel from top antibody companies will share their insights on hot issues in antibody patenting.

*Moderator: Timothy J. Shea, Jr., Director, Sterne, Kessler, Goldstein & Fox P.L.L.C.*

*Panelists: Michael Braunagel, Ph.D., Director, Strategic Alliances and Licensing, Affitech AS, Norway; Diane Wilcock, Ph.D., Director, Intellectual Property, Xoma (US) LLC; Jennifer A. Zarutskie, Ph.D., J.D., Director of Intellectual Property, Patent Counsel, Dyax Corp.*

#### 12:00 Technology Workshop

#### Clinical Trials Using Potelligent® Mabs



Depletion of the target cell population expressing a specific antigen is one of the therapeutic concepts of antibody drugs. Potelligent® technology enhances the ADCC activity of therapeutic antibodies, which is the key mechanism of action of those depleting antibodies. In this presentation, clinical studies using Potelligent® antibodies in the oncology and inflammatory areas will be discussed.

**Masamichi Koike, Ph.D.,** *President and Chief Executive Officer, BioWa, Inc.*

#### 12:30 Networking Luncheon, Last Chance for Exhibit and Poster Viewing

### Session IV: Clinical Development of Non-Cancer Therapeutics (1)

#### 2:00 Announcements and Chairperson's Opening Remarks

**Trudi Veldman, Ph.D.,** *Director, Biologics Generation, Abbott Laboratories*

### Keynote Presentation

#### 2:05 Monoclonal Antibody First-In-Man Studies: A Regulatory Perspective and Recommendations

Triggered by the TGN1412 catastrophe, procedures and criteria used in the authorization of clinical trials had to be rethought. As a consequence, a new EMEA guideline for First-In-Man studies was published. It outlines requirements for preclinical development and for the clinical protocol with the aim of health risk mitigation for the participants. Clinical trial authorization in the EU is the responsibility of the national competent authorities, in Germany represented by the Paul-Ehrlich-Institute with respect to antibody therapeutics. An overview of current regulatory thinking is given.

**Petra M. Schmitt, Ph.D.,** *Preclinical and Quality Assessor, Federal Agency for Sera and Vaccines, Division of Immunology, Section 3/2 Monoclonal and Polyclonal Antibodies Paul-Ehrlich-Institute, Germany*

#### 2:45 Monoclonal Antibodies in Development for the Treatment of Asthma – Anti-IL-13 (CAT-354), Anti-IL-9 (MEDI-528) and Anti-IL-5Ra (MEDI-563)

Asthma is an inflammatory disorder of the airways associated with airway remodeling, mucus hypersecretion and reversible airway obstruction. Inflammation in part is mediated cytokines such as IL-5, IL-9 and IL-13, each of which orchestrates different aspects of asthma pathology. We have designed specific monoclonal antibodies that allow for the efficient interference with IL-13, IL-9 and IL5Ra signaling pathways. The relative contribution of inhibiting either pathway for the treatment of asthma will be discussed in detail.

**Roland Kolbeck, Ph.D.,** *Director Respiratory, Inflammation & Autoimmunity, MedImmune, Inc.*

3:15 **Efficacy and Safety of NGF Blocking Antibody, Tanezumab (PF04383119 or RN624), in Treating Moderate to Severe Pain Due to Osteoarthritis**

This abstract was not available at the time of printing the brochure. For up to date program information, please visit [www.IBCLifeSciences.com/AntibodyTher](http://www.IBCLifeSciences.com/AntibodyTher)

**John C. Lin, M.D., Ph.D.**, Senior Director, Neuroscience, Rinat, Pfizer Inc.

3:45 *Networking Refreshment Break*

4:15 **Bapineuzumab for the Potential Treatment of Alzheimer's Disease**

This abstract was not available at the time of printing the brochure. For up to date program information, please visit [www.IBCLifeSciences.com/AntibodyTher](http://www.IBCLifeSciences.com/AntibodyTher)

**Dale B. Schenk, Ph.D.**, Executive Vice President and Chief Scientific Officer, Elan Pharmaceuticals, Inc.

4:45 **Immunoprophylaxis of RSV Infection: Advancing from RSV-IGIV to Palivizumab and Motavizumab**

For preventing respiratory syncytial virus (RSV) infection, we have successfully developed two prophylactic antibody products. Palivizumab, a humanized mAb that binds to the RSV F protein, is a potent anti-RSV mAb that is about 50-fold more potent than RSV-IGIV. A more potent second-generation mAb, motavizumab, is currently being investigated in Phase 3 clinical trials. A third generation mAb has been generated with the intent to extend the serum half-life of the mAb in humans.

**Herren Wu, Ph.D.**, Vice President, Head, Department of Antibody Discovery and Protein Engineering, and Global Head of Technology, MedImmune, Inc.

5:15 **Certolizumab Pegol (Pegylated Fab' blocking TNF $\alpha$ ) Cimzia®**

The novel, humanized antibody fragment, Cimzia®, binds TNF $\alpha$  univalently with high affinity, and has enhanced pharmacokinetic properties through site-specific attachment of polyethylene glycol. Cimzia was approved by FDA for treatment of Crohn's Disease earlier this year. In Phase III studies in rheumatoid arthritis, significant reduction in joint destruction and rapid improvement in signs and symptoms of the disease were observed.

**Tim Bourne, Ph.D.**, Senior Director, Inflammation Portfolio, UCB Celltech, United Kingdom

5:45 *Close of Session*

7:30 *Networking Coffee*

**Session V: Clinical Development of Non-Cancer Therapeutics (2)**

8:35 **Announcements and Chairperson's Opening Remarks**

**Mark R. Alfenito, Ph.D.**, President, KaloBios Pharmaceuticals Inc.

8:45 **Development of KB001, a Targeted Anti-Bacterial Therapeutic**

*Pseudomonas aeruginosa* uses the syringe-like Type Three Secretion System (TTSS) to kill host cells and induce tissue inflammation. KB001, a PEGylated, near germline, "humaneered", Fab' fragment with long half life, low immunogenicity, and resistance to protease degradation, binds with high affinity to the well conserved PcrV protein on the tip of the TTSS, rendering it non-functional. Preclinical and phase 1 results will be presented and clinical trials in cystic fibrosis and mechanically-ventilated patients described.

**Tillman Pearce, M.D.**, Chief Medical Officer, KaloBios Pharmaceuticals, Inc.

9:15 **Clinical Development of Ibalizumab, an Anti-CD4 HIV Uptake Inhibitor**

Ibalizumab (formerly TNX-355) is a humanized immunoglobulin G (IgG) isotype 4 monoclonal antibody (mAb) currently in Phase 2 clinical development for the treatment of human immunodeficiency virus (HIV) disease. A Phase 1/ 2a trial for HIV prevention is also planned. Ibalizumab binds to a conformational epitope on domain 2 of CD4, a glycoprotein receptor expressed on the surface of T-helper cells (CD4), inhibiting HIV entry into target cells.

**Stanley Lewis, M.D.**, Chief Medical Officer, Taimed Biologics

9:45 *Networking Refreshment Break*

10:15 **The Discovery and Development of a Novel Anti-Cytokine Antibody ALD518**

Alder Biopharmaceuticals has developed a system that enables the identification of single to double-digit picomolar affinity antibodies that can be quickly humanized with complete potency recovery. Clinical supplies of these molecules are derived from a *Pichia pastoris* expression system that can provide rapid access to drug supply. The discovery and development of ALD518 will be used to illustrate the capabilities of the system and its agility to quickly move from project inception to first dose in man.

**John A. Latham, Ph.D.**, Chief Scientific Officer, Alder Biopharmaceuticals

10:45 **Golimumab, a Human Anti-TNF $\alpha$  Monoclonal Antibody (mAb), for the Treatment of Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis**

A Marketing Authorization Application (MAA) was submitted to EMEA in February 2008 and a Biologics License Application (BLA) to the U.S. FDA in June 2008 requesting the approval of Golimumab as a monthly subcutaneous treatment for adults with active forms of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. Golimumab is being studied as an every four-week subcutaneous injection and as an intravenous infusion therapy. The improved pharmacokinetic characteristics for golimumab and its exposure-response relationship will be discussed.

**Zhenhua (Mike) Xu, Ph.D., F.C.P.**, Associate Director, Clinical Pharmacology, Centocor R&D/Johnson & Johnson

11:15 **PRO 140: A Humanized CCR5 Monoclonal Antibody for HIV-1 Therapy**

New drugs are needed to manage better the lifelong care of HIV-infected individuals. PRO 140 binds the chemokine receptor CCR5, which most HIV-1 strains use to enter CD4+ cells. Laboratory studies indicate that PRO 140 represents a distinct class of CCR5 inhibitor. Phase 1b monotherapy testing established proof of concept for PRO 140 as a potent antiretroviral agent with extended activity, and phase 2 studies have been initiated to evaluate intravenous and subcutaneous forms of PRO 140.

**William C. Olson, Ph.D.**, Vice President, Research and Development, Progenics Pharmaceuticals, Inc.

11:45 *Close of Antibody Therapeutics Meeting; Delegates are Invited to Attend the Afternoon Session of Antibody Engineering*

*"The meeting provided a unique opportunity to learn of the current progress in the development of novel antibody-based structure and scaffolds"*

Dr. Gregory Adams, Fox Chase Cancer Center

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Codon Devices, Inc. is a biotechnology company focused on enabling commercial applications of synthetic biology. The company uses proprietary design and construction methods to rapidly engineer biological components for improved function. These methods reduce the risk and time associated with bioproduct development, creating significant value for our partners in the biotechnology, pharmaceutical, and agriculture sectors.



MedImmune is the worldwide biologics business for the AstraZeneca Group. The company has approximately 3,000 employees worldwide and is headquartered in Gaithersburg, Maryland with facilities in Pennsylvania, California, Kentucky, the United Kingdom, and the Netherlands. With two marketed products and an advancing pipeline of promising candidates in the areas of infection, oncology, respiratory disease and inflammation, cardiovascular/gastrointestinal disease and neuroscience, MedImmune strives to provide better medicines to patients, new medical options for physicians and rewarding careers to employees.



MorphoSys AG, located in Martinsried/Munich, Germany, is one of the world's leading biotechnology companies focusing on fully human antibodies. With its unique technologies, MorphoSys is developing the next generation of antibodies, which can be used to treat diseases and for research and diagnostics purposes. The Company, founded in 1992, possesses the unique HuCAL technology (the Human Combinatorial Antibody Library). This library comprises more than ten billion different, fully human antibodies.



The PERCIVIA PER.C6® Development Center develops the PER.C6® human cell line for recombinant proteins. PERCIVIA offers an integrated technology platform for protein production. The PERC.6® cell line generation technology offers cell culture development, up and downstream processes, design, scale-up, technology transfer, and regulatory support.



XOMA is a leader in the discovery, development and manufacture of therapeutic antibodies and has a fully integrated infrastructure including preclinical through manufacturing. XOMA leverages a broad technology platform of six commercial antibody phage display libraries, custom human antibody phage display libraries, hybridoma, Human Engineering™ and affinity maturation technologies.

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<b>4-Day Conference Plus Workshop (D8172):</b> Sunday-Thursday Access to the Sunday Workshop and Antibody Engineering and Antibody Therapeutics	<input type="checkbox"/> \$1999	<input type="checkbox"/> \$2099	<input type="checkbox"/> \$2199	<input type="checkbox"/> \$2299
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Please make check(s) (in U.S. funds drawn on a U.S. bank) payable to IBC Life Sciences and attach to the registration form. Confirmation of your booking will be sent. Wire Transfer: Please tell your bank to include the conference code D8172, invoice number, person attending, name and date of the conference in the transfer instructions. Wire transfers and EFT payments: please contact accounts receivable at [account-liaison@informausa.com](mailto:account-liaison@informausa.com) for banking details

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Name (as appears on card) \_\_\_\_\_ Signature \_\_\_\_\_

**Unable to Attend? Purchase the Conference CD-ROM.** The conference CD-ROM containing a selection of speaker presentations will be available for purchase following the event.

I cannot attend. Please send \_\_\_\_\_ CD-ROM(s). Enclosed is my payment for \$399 each, plus shipping and handling (\$25 in the U.S., \$45 outside the U.S.).

**TRAVEL RESERVATIONS:** For all air travel arrangements, including international, please call or write IBC's official air travel agency, Commonwealth Travel Advisors, to book your travel. E-mail: [jdwyer@traveladvisors.com](mailto:jdwyer@traveladvisors.com) or call: USA: 888.703.4286 or 508.366.3660; International: 1.508.366.3660. Please be certain to mention IBC along with the conference title, dates, and conference code D8172 when e-mailing or calling. Please note there is a \$29.00 booking fee for using this service.

**DISCOUNTED HOTEL RESERVATIONS:** To be included in IBC's dedicated room block for this conference call the hotel directly before **November 16, 2008** to receive the IBC discounted rate. Please be sure to mention Antibody Engineering along with IBC and make your reservations as soon as possible. Please note that the room block is limited and we recommend making your reservations as soon as possible as availability is not guaranteed.

## Additional Registration Information

**Unauthorized solicitation is strictly prohibited at this event and failure to comply could result in revocation of your access privileges. This is a trade only event. For your safety and security, a photo identification and industry related business card are required at the conference check-in to complete your registration.**

Program content and speakers subject to change. Children under 18 are not permitted in the exhibit hall under any circumstances. Conference badges are non-transferable and lost badges will not be replaced without payment of the full conference registration fee.

**Other Information:** Main conference registration fee includes two luncheons, cocktail receptions, technology workshops, refreshments, access to exhibit hall and CD ROM with speaker documentation. Please note that payment is required in advance of the conference. Please make check(s) (in U.S. funds drawn on a U.S. bank) payable to IBC Life Sciences and attach to the registration form. Confirmation of your booking will be sent. Should you elect to pay by MasterCard, Visa or American Express, please send your credit card number, expiration date, name as it appears on card and signature along with the registration form.

### REGISTRATION SUBSTITUTIONS/CANCELLATIONS:

In order to receive a prompt refund, your notice of cancellation must be received in writing (by letter or fax) 10 business days before the conference. We regret cancellations will not be accepted after that date. However, we will be pleased to transfer your registration to another member of your company at any time. If you plan to send someone in your place, please notify us as soon as possible so that materials can be prepared. All cancellations will be subject to a \$395 processing fee. If IBC cancels an event, IBC is not responsible for any airfare, hotel or other costs incurred by registrants. Speakers subject to change without notice.

**SPECIAL NEEDS:** If you have a disability or special dietary needs, please let us know in order that we may address your special needs for your attendance at this show. Please send your special needs via email to [custserv@ibcusa.com](mailto:custserv@ibcusa.com) or fax 508-616-5522.

For security precautions, a photo identification will be required of ALL attendees at check-in.



IBC's 19th Annual  
International Conference

December 7-11, 2008  
Sheraton San Diego Hotel and Marina San Diego, CA

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- Intrabodies Revisited
- Novel Antibody Targets and Applications
- Antibodies in a Complex Environment: Target Selection in Relation to Efficacy
- Mechanism of Antibody Action Revisited

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Co-located Event: IBC's 6th Annual

December 9-11, 2008

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