

## Tuesday, June 3, 2008

### 09:00 Welcome, Introduction and Opening Remarks

*Karoline Bechtold-Peters, Co-Chair,  
Boehringer-Ingelheim Pharma GmbH & Co KG,  
Biberach an der Riss DE*  
*Wim Jiskoot, Co-Chair, Leiden/Amsterdam Center  
for Drug Research (LACDR), Leiden NL*

### Keynote presentation

09:15-10:00  
Evolving technologies of antibody engineering  
*Michael Neuberger, Trinity College Cambridge,  
Cambridge UK*

### Session I: Design of antibodies and antibody mimetics

10:00 - 11:10  
**Chairman:** *René Hoet, Genmab A/S,  
Utrecht NL*

10:00 SMIPs and Scorpions: Potent and selective  
single-chain mono- and multi-specific  
therapeutics  
*Alan Wahl, Trubion Pharmaceuticals Inc.,  
Seattle, WA USA*

10:35 Single domain camel antibodies  
*Serge Muyldermans, Free University of  
Brussels, Brussels BE*

### 11:10 Coffee/Tea

### Session II: Upstream development

11:40 - 12:50  
**Chairman:** *Sven Stegemann, Capsugel,  
Bornem BE*

11:40 Automation in antibody discovery and  
development  
*Arnout Gerritsen, Genmab BV, Utrecht NL*

12:15 Plant derived antibodies and how to  
overcome current challenges in post-  
translation  
*Rainer Fischer, Fraunhofer-Institut für  
Molekularbiologie und Angewandte  
Oekologie, Aachen DE*

### 12:50 Lunch

### Session III: Downstream development

14:20 – 15:30  
**Chairman:** *Wayne R Gombotz, Omeros  
Corporation, Seattle WA USA*

14:20 Use of membrane adsorbers for impurity  
removal  
*Lee Allen, Lonza Biologics, Slough UK*

14:55 Viral safety studies – Current views  
*Klaus Kellings, NewLab BioQuality AG,  
Ekrath DE*

### 15:30 Coffee/Tea

### PODIUM DISCUSSION

**16:00-18:00**  
(Prepared questions, participants to forward  
questions on cards, panel discussion)

### Welcome Reception

18:30 Bus shuttle from Crowne Plaza to the  
'Castle of Heidelberg'

## Wednesday, June 4, 2008

### Session IV: Physical characterisation and protein analytics

09:00 – 10:10  
**Chairman:** *Barry D Moore, XstalBio, Glasgow  
UK*

09:00 The role of mass spectrometry in process  
development of therapeutic proteins  
*Niklas Engler, Roche Diagnostics GmbH,  
Penzberg DE*

09:35 Platform analytics for high throughput  
antibody development  
*Robert W Bailey, Amgen Inc, Seattle WA  
USA*

### 10:10 Coffee/Tea

### Session V: Pharmacokinetics

10:40 – 11:50  
**Chairman:** *René Hoet, Genmab BV,  
Utrecht NL*

10:40 Predicting the exposure and effect of monoclonal antibodies using PK-PD modelling  
*Bart Ploeger, LAP&P Consultants BV, Leiden NL*

11:15 Antibody transport across biological barriers  
*Mark Gumbleton, University of Cardiff, Cardiff UK*

### **Session VI: Safety and immunology**

11:50 – 13:00

**Chairman:** *Karoline Bechtold-Peters, Boehringer-Ingelheim Pharma GmbH & Co KG, Biberach an der Riss DE*

11:50 Immunogenicity of cytokine-modulating biopharmaceuticals – an inconvenient truth  
*Klaus Bendtzen, Institute for Inflammation Research, Rigshospitalet and BioMonitor Ltd, Copenhagen DK*

12:25 Report on the Tegenero case  
*Nicki Panoskaltsis, Imperial College London, Northwick Park & St Mark's Campus UK*

**13:00 Lunch**

### **Session VII: Aggregates and protein immobilization**

14:30 – 15:40

**Chairman:** *Wim Jiskoot, Leiden/Amsterdam Center for Drug Research, Leiden NL*

14:30 Protein aggregation – Mechanism, thermodynamic driving forces and kinetics  
*Eva Y Chi, University of Chicago, Chicago IL USA*

15:05 Exploiting precipitation and crystallization of monoclonal antibodies for drug development  
*Karoline Bechtold-Peters, Boehringer-Ingelheim Pharma GmbH & Co KG, Biberach an der Riss DE*

**15:40 Coffee/Tea**

### **PODIUM DISCUSSION**

**16:10-18:10**

(Prepared questions, participants to forward questions on cards, panel discussion)

**Thursday, June 5, 2008**

### **Session VIII: Pharmaceutical aspects**

08:30 – 09:40

**Chairman:** *Barry D Moore, XstalBio, Glasgow UK*

08:30 High throughput formulation of monoclonal antibodies  
*Tudor Arvinte, University of Geneva, Geneva CH*

09:05 Formulation of biologics in relation to bulk storage options  
*Satish K Singh, Pfizer Global Biologics Inc, Chesterfield MO USA*

### **Session IX: Clinical aspects**

09:40 – 10:50

**Chairman:** *Heiko E von der Leyen, Hannover Clinical Trial Center GmbH, Hannover DE*

09:40 Transition from early phases to phase III  
*Ulrich Granzer, Granzer Regulatory Consulting & Services, Munich DE*

10:15 Development of a novel therapeutic antibody directed against MRSA  
*Knut Ohlsen, University of Würzburg, Würzburg DE*

**10:50 Coffee/Tea**

### **Session X: Regulatory aspects**

11:20 – 12:30

**Chairman:** *Sven Stegemann, Capsugel, Bornem BE*

11:20 Monoclonal antibodies and high-risk medicinal products  
*Jan Müller-Berghaus, Paul-Ehrlich-Institute, Langen DE*

11:55 Is the biosimilar paradigm applicable to monoclonal antibodies?  
*Huib Schellekens, Utrecht University, Utrecht University, Utrecht NL*

**12.30      Lunch**

**Session XI: New trends/Market  
development**

14:00 – 14:35

**Chairman:** *Inge Mühldorfer, Rentschler  
Biotechnologie GmbH, Laupheim DE*

14:00 Therapeutic antibodies: Trends and future  
developments

*René Hoet, Genmab BV,  
Utrecht NL*

**PODIUM DISCUSSION**

**14:35-15:35**

(Prepared questions, participants to forward  
questions on cards, panel discussion)

**Concluding remarks**

**15:35 – 16:00**