

DAY 2 01 APRIL 2011

**Session 4: EARLY DEVELOPMENT OF ADVANCED THERAPIES**

Chair: *K Breithaupt-Grögler, Frankfurt, L Van Bortel, Gent*

9:00 Gene therapy studies

*J G Dickson, London*

9:30 Stem cell therapy studies

*S Janssens, Leuven*

10:00 Tissue-engineered products

*F Luyten, Leuven*

10:30 Coffee Break

**11:00 PARALLEL WORKSHOPS**

**WS 5** Preparation and management of Phase I studies with stem cell therapy

**WS 6** Modelling and simulation to help MABEL definition

*B Laurijssens, Chambonas, S Martin, Sandwich*

**WS 7** Ethical dilemmas in modern therapies

*I Klingmann, Brussels, C Heberlein, Ebmingen*

**WS 8** Practical application of risk assessment and management in early clinical development

*H Caplain, Chilly-Mazarin, P Van der Auwera, Basle*

12:30 Lunch Break

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**BAPU:** [www.bapu.be](http://www.bapu.be)  
**AHPPI:** [www.ahppi.org.uk](http://www.ahppi.org.uk)

**Session 5: STRENGTHENING EUROPEAN HUMAN PHARMACOLOGY FOR THE EARLY DEVELOPMENT OF MODERN THERAPIES**

Chair: *J de Hoon, Leuven, Y Donazzolo, Lyon*

13:30 Open forum discussion:

Need for a uniform European accreditation system for Phase I units?

*Introduction: U Lorch, London*

14:15 Open forum discussion:

Need for a uniform European registration system for volunteer participation?

*Introduction: A Peremans, Antwerp*

15:00 Open forum discussion:

Need for SAE-reporting in Phase I studies across countries?

*Introduction: A Patat, Rennes*

15:45 Closing remarks

*I Klingmann, Brussels*

16:00 End of conference

**Venue:** Langenbeck-Virchow Haus  
Luisenstr. 58/59, 10117 Berlin  
Phone: +49 (30) 2887 9834

**Date:** Thursday, 31 March & Friday, 01 April 2011

**Conference fees:**

340,00 €	Members of AGAH, CPI, AHPPI, BAPU
400,00 €	Non-members
250,00 €	Junior scientists
200,00 €	Day ticket

50,00 € reduction for early bird registration prior to 15 January 2011

**AGAH General Assembly: 30 March 2011, 19:00h**



Joint Conference of European Human Pharmacology Societies

**Exploratory Development of Modern Therapies – Biologicals, Advanced Therapies and Drug-Device Combinations**



31 March & 01 April 2011, Berlin, Germany

**Second Announcement**

**Human Pharmacology** is still a relatively young discipline. Only in the 1980s clinical pharmacologists performing Phase I studies founded dedicated scientific associations to exchange experience, to foster systematic research and to harmonise quality standards. Since then great progress has been made in early drug development of small molecules for many different indications. Human pharmacology today is crucial for early go/no-go decisions. The growing number of biologicals, new advanced therapies and innovative modes of drug application like drug/device combinations or nanoparticles call for new scientific tools. Human pharmacologists have to adapt to completely new mechanisms of action, pharmacological characteristics, models, methodologies and techniques in Phase I/II clinical trials.

The best way to compile the current level of knowledge and to exchange the sparse experience on new methodologies is international collaboration. The German AGAH e.V, the French Club Phase I, the Belgian BAPU and the British AHPPI decided to join forces and have the great pleasure to invite you to their 1<sup>st</sup> joint conference. This meeting will update you on new approaches in exploratory development of modern therapies and provides ample opportunity to discuss ideas, strategies, methods, technologies and experience with the early development of biologicals, advanced therapies and drug-device combinations in 2 days of plenary sessions and workshops.

*Celebrating its 20<sup>th</sup> anniversary, AGAH is proud to welcome three sister associations to Berlin, where it was founded in 1991. We are happy to celebrate the development and continuous growth of AGAH, providing a "home" for the majority of human pharmacologists working in pharmaceutical companies, CROs and academic units in Germany.*

## DAY 1 31 MARCH 2011

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09:00 Welcome and introduction to the first joint meeting of AGAH, Club Phase I, BAPU, AHPPI

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### Session 1: PRINCIPLES OF EARLY DEVELOPMENT OF BIOLOGICALS

*Chairs: A Patat, Rennes, I Klingmann, Brussels*

9:15 Impact of the ICH-M3 guideline on the early development of biologicals

*S Plassmann, Munich*

9:45 Predictivity of toxicological tests for the early development of biologicals

*J-J Legrand, Evreux*

10:15 Fixed dosing versus weight-based dosing in clinical development of biotherapeutic proteins

*D Wang, La Lolla-California*

10:45 Coffee Break

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### Session 2: REGULATORY ASPECTS

*Chairs: M Hammond, Slough, O Van Schoor, Antwerp*

11:15 EMA's role and responsibilities for the development of modern therapies

*E Flory, Langen*

11:45 The role and responsibilities of a national competent authority in the development of modern therapies

*E Godfrey, London*

12:15 Signal detection and risk management in early clinical development

*H Caplain, Chilly-Mazarin, P Van der Auwera, Basle*

12:45 Lunch Break

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### 14:00 PARALLEL WORKSHOPS

**WS 1** Early clinical development of vaccines  
*M Hammond, London*

**WS 2** QT-Studies for biologicals  
*P L'Hostis, Rennes, J Täubel, London*

**WS 3** Stopping rules in exploratory drug development  
*A Patat, Rennes*

**WS 4** Biologicals vs. small molecules – What's the difference?  
*P Lloyd, Redhill, G Narayanan, London*

15:30 Coffee Break

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### Session 3: EARLY DEVELOPMENT OF DRUG-DEVICE COMBINATIONS

*Chairs: T Thomsen, Andernach, U Lorch, London*

16:00 Toxicological programme and predictivity of toxicological results for drug-device combinations

*A McLean, London*

16:30 Regulatory background for medicinal product / medical device development

*T Sudhop, Bonn*

17:00 Example for an early drug-device development plan

*B Schug, Oberursel*

17:30 End of Day 1

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19:30 Social Event