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
R Yanez, Egham

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
G Tiedemann, Rostock, D Sawitzky, Leipzig

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, Ebmatingen

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

Inquiries: Intercom Kongresse GmbH
A. Blömeke
Eppendorfer Baum 39a
20249 Hamburg, Germany
T.: +49 (0)40 4806 1061
F.: +49 (0)40 4806 1066
abloemeke@intercom.de

AGAH: www.agah.info
CP1: www.clubphase1.fr
BAPU: www.bapu.be
AHPPI: 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

AGAH
Association for Applied Human Pharmacology

20th Anniversary

Club Phase 1

BELGIAN ASSOCIATION OF PHASE-I UNITS
bapu

AHPPI

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

Fourth 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 1st 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 **20th 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

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

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

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

14:00 PARALLEL WORKSHOPS

WS 1 Early clinical development of vaccines
M Peeters, Rixensart, G Hale, Abingdon

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

WS 3 Stopping rules in exploratory drug development
A Patat, Rennes, Y Donazzolo, Lyon

WS 4 Biologicals vs. small molecules – What's the difference?
P Lloyd, Horsham, G Narayan, London

15:30 Coffee Break

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

19:30 Conference Dinner