

## Thursday - April 26, 2007

08.30 **Registration and coffee**

09.00 Opening remarks

*Presidents AGAH and Club Phase I*

### Session I Current approaches in human pharmacology

*Chair: Y. Donazzolo, Gières, T. Thomsen, Andernach*

09.05 Pharmacokinetics and bioavailability: Examples from various body fluids *W. Cavello, Monheim*

09.40 Tolerability and safety: Predictability of QT prolongation in healthy subjects from preclinical experiments *H. Caplain, Paris*

10.15 Dose/concentration-effect relationship: Biomarkers in CNS drug development - effects of opioid analgesics  
*F. Fliegert, Aix-la-Chapelle*

10.50 **Coffee break**

11.15 **Parallel workshops**

- An introduction to state of the art pharmacokinetics  
*W. Cavello, Monheim*
- PK and PD as predictors of a clinical effect  
*J. Grevel, Verona*
- Need for and approaches to a European trial subjects database  
*B. Schug, Oberursel, R. Schäfer, Frankfurt, A. Peremanns, Brussels, Y. Donazzolo, Gières, T. Thomsen, Andernach*
- Designs of human pharmacology trials for paediatric populations  
*E. Jacqz-Aigrain, Paris, H. Seyberth, Landau*
- Current regulatory developments relevant to human pharmacology in the EU  
*I. Klingmann, Brussels, C. Schneider, Langen*

12.30 **Lunch break and Poster Session**

### Session II What is human pharmacology expected to deliver in the future?

*Chair: K. Breithaupt-Grügler, Frankfurt, A. Patat, Rennes*

14.00 From understanding the disease to implementing the diagnostic biomarker and the effective treatment—practical examples  
*S. Stürzebecher, Aix-la-Chapelle*

14.35 Development of meaningful interaction studies for combination therapies  
*J. van Gerven, Leiden*

15.10 Imaging techniques in the early development of new compounds  
*P. Danjou, Paris*

15.45 **Coffee break**

16.00 Round table discussion

*Chair: I. Klingmann, Brussels, I. Paty, Paris*

Will human pharmacology be needed to develop individualized treatments?

*Participants: D. Austin, London, H. Caplain, Paris, T. Sudhop, Bonn, S. Stürzebecher, Aix-La-Chapelle, M. Zühlendorf, Basle*

17.15 End of Day I

18.30 **Conference Dinner Event**



## Friday - April 27, 2007

### Session III Challenges and limitations of human pharmacology

*Chair: L. Tritsman, Brussels, J. van Gerven, Leiden*

08.30 Human pharmacology for biologicals—first into man  
*D. Austin, London*

09.00 Genotyping: A reliable predictor for safety and tolerability?  
*M. Schwab, Stuttgart*

09.30 Interpretation of early safety signals  
*M. Sibille, Lyon*

10.00 **Coffee break**

10.30 **Parallel workshops:**

- Microdosing: myths and reality; scientific, regulatory and financial perspectives  
*J. de Hoon, Leuven, D. Pegg, Ann Arbor, C. Schneider, Langen, C. Garner, Haslington*
- Predictability of pharmacological methods  
*J-L. Pinguier, Paris*
- Biomarkers in specific areas  
*M. Zühlendorf, Basle*
- Sustainability of the pharmaceutical development pipeline: methods, facts and perspectives  
*W. Seifert, Berlin*
- Do population kinetics work without dense data sampling?  
*N.O. Hoem, Hamburg*

12.00 **Lunch break and Poster Session**

### Session IV Getting fit for the future of human pharmacology

*Chair: H. Caplain, Paris, C. Hinz, Rheinau*

13.30 Scientific requirements: Perspective of an editor for an international clinical pharmacology journal  
*U. Fuhr, Cologne*

14.00 Oxford debate on how to establish tolerability and safety—MTD versus pharmacological activity  
*M. Sibille, Lyon, J. van Gerven, Leiden*

14.45 New regulatory requirements for first into man studies in Germany and France  
*T. Sudhop, BfArM, Bonn, D. Tremblay AFSSAPS, Paris*

15.45 Closing remarks  
*H. Fuder, Hamburg*

# Positioning Human Pharmacology for the Future

## Second Joint Annual Meeting Club Phase I and AGAH

**T**his second joint meeting of Club Phase 1 - the French Association of Early Human Drug Development — and AGAH — the German Association for Applied Human Pharmacology - addresses a vital question: „How to position human pharmacology for the future?“

Which role can and should human pharmacology play in the development of new classes of drugs and biologicals? This meeting will attempt to find answers to these questions and also to highlight technical-, safety- and regulatory issues impacting on clinical development.

AGAH and Club Phase 1 are delighted to welcome our Belgian Colleagues from BAPU to this meeting and are looking forward to their scientific contributions and collaboration. This will certainly foster the widespread mutual interest for a pan European collaboration of human pharmacologists

## CONGRESS INFORMATION

|                      |   |
|----------------------|---|
| <b>Date</b>          | April 26 and 27, 2007   |
| <b>Venue</b>         | MARITIM HOTEL BAD HOMBURG<br>Kurhaushotel/Kongresszentrum<br>Ludwigstraße 3<br>61348 Bad Homburg vor der Höhe<br>Germany  |
| Telephone            | +49 (0)6172 660-0   |
| Fax                  | +49 (0)6172 660-100   |
| <b>Registration</b>  | INTERCOM Dresden<br>Antje Blömeke<br>Zellescher Weg 3<br>01069 Dresden<br>Germany   |
| Telephone            | +49 (0)351 4633 3014  |
| Fax                  | +49 (0)351 4633 7049  |
| E-mail               | abloemeke@intercom.de   |
| Homepage             | www.agah-web.de   |
| <b>Fees</b>          | 250,00 € Member (early registration)<br>275,00 € Member<br>275,00 € Nonmember (early registration)<br>300,00 € Nonmember<br>200,00 € Junior Scientist<br>125,00 € Junior Poster (Member)<br>150,00 € Junior Poster (Nonmember)<br>200,00 € Day Ticket<br>275,00 € Industry Exposition Staff |
|                      | Early bird reductions applied for registration up to January 31, 2007.  |
|                      | Fees include admission to all sessions, lunches and coffee breaks.  |
| <b>Accommodation</b> | A number of rooms at special discounted rates are available at the Venue.   |



AGAH

## 2nd Joint Annual Meeting 2007



# Positioning Human Pharmacology for the Future

April 26 and 27, 2007

Bad Homburg v.d.H., Germany