CONGRESS INFORMATION

Date:
April 18 – 19, 2008

Conference venue:
Leonardo Hotel Weimar
Belvederer Allee 25
D-99425 Weimar, Germany
Tel.: +49 (0) 3643 - 722 - 0
Fax: +49 (0) 3643 - 722 - 2320
Web: www.leonardo-hotels.com

Registration:
INTERCOM Dresden GmbH
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Conference fees:

- 275 Euro Member
- 325 Euro Nonmember
- 200 Euro Junior Scientist*
- 200 Euro Day Ticket
- 275 Euro Industry Exposition Staff

** under the age of 30 years*

Fees include admission to all sessions, lunches and coffee breaks.

Accommodation:
A number of rooms at special discounted rates are blocked and available via INTERCOM Dresden GmbH.

PROGRAM COMMITEE

Ingrid Klingmann, Kerstin Breithaupt-Grögler, Ulrich Feifel, Hermann Fuder, Christian Hinze, Wolfgang Timmer

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Belvedere Castle in Weimar

AGAH
Arbeitsgemeinschaft
für angewandte
Humanpharmakologie e.V.

Association for Applied
Human Pharmacology

THIRD ANNOUNCEMENT

ANNUAL MEETING 2008

SAFETY AND RISK MANAGEMENT IN TRANSLATIONAL MEDICINE

April 18 – 19, 2008
in Weimar (Germany)

THURSDAY, APRIL 17, 2008

18:00	Get-together
19:00	AGAH General Assembly

SAFETY AND RISK MANAGEMENT IN TRANSLATIONAL MEDICINE

Drug development must find a balance between the excitement of discovering new treatment options and the protection of subjects participating in clinical trials. Healthy volunteers and staff responsible for their well-being are relying on the adequacy of the procedures applied to minimize risk during the exploratory phases. Hence, the results of pre-clinical pharmacological models, toxicological studies and foregoing clinical trials in healthy volunteers and patients are expected to be of predictive value for the next step. With the increasing number of biologicals and compounds with completely new mechanisms of action this concept may no longer be satisfactory, as has been painfully experienced with the first administration of TGN1412 to healthy volunteers.

Today's drug development is subjected to a highly regulated and segmented setting. A closer cooperation between pre-clinical and clinical experts is essential to identify and select the appropriate investigational tools, to early identify potential safety issues, and to translate the findings of exploratory trials into efficacious and safe new drugs.

This conference focuses on finding appropriate techniques and strategic approaches to improve the safety of study participants, to minimize risk, and to improve the predictive value of the safety profile for a new compound. Concepts and guidelines for the new regulatory environment for Phase I studies in the EU will be presented. Experts from all research areas involved will share their experience, discuss the limitations of interpreting the clinical relevance of their studies' results and present concepts for improving the drug development process.

The meeting will be held in English.

FRIDAY, APRIL 18, 2008

08:30	Registration
09:00	Opening remarks *(Torben Thomsen)*

Session I — **The Predictive Relevance of Preclinical Safety Information**

Chair: Hermann Fuder, Michael Zühlsdorf

09:10	Fundamental international regulatory requirements for human trials (Eckhard von Keutz, Wuppertal)
09:40	Implications of pharmacological models for risk assessment *(Ulrich Kalinke, Langen)*
10:10	Can toxicogenomics predict safety? *(Frank Staedtler, Basel)*
10:40	Relevance of toxicological findings for drug safety in humans *(Klaus Olejniczak, Bonn)*
11:10	Coffee Break
11:40	**Parallel workshops:** • *Studies with radiolabelled drugs in Germany (Gerhard Scheuch, Gauting)* • *Literature search and how to improve knowledge management (Oliver Renn, Biberach)* • *Comparison of International First-in-Man Guidelines (Ingrid Klingmann, Brussels)*
13:10	Lunch

Session II — **The Predictive Relevance of Human Pharmacology Trials for Drug Safety**

Chair: Gerd Mikus, Wolfgang Timmer

14:30	Rationale for determining the MTD – which findings are really important? *(Joachim Gerloff, Würzburg)*
15:00	Relevance of Phase I SAEs, SUSARs and important medical events for patient safety *(Michel Sibille, Lyon)*
15:30	How predictive is QTc prolongation really? *(Wilhelm Haverkamp, Berlin)*
16:00	Coffee Break

Session III — **The expedited CTA – a suitable approach for Europe?**

Chair: Ulrich Feifel, Thomas Sudhop

16:30	A Panel and Open Forum Discussion *(T. Reum, Bonn; E. Stahl, Bonn; S. Hockertz, Seelze; W. Beier, Munich; E. von Keutz, Wuppertal)*
19:30	**Conference Dinner *(Alte Remise, Tiefurt)***

SATURDAY, APRIL 19, 2008

Session IV — **Integrated Preclinical and Clinical Safety Assessment and Applications**

Chair: Kerstin Breithaupt, Torben Thomsen

08:30	Assessment of drug-relationship of AEs in Phase I *(Matthias Großmann, Berlin)*
09:00	Relevance of pre-clinical findings for the interpretation of Adverse Events *(Timothy Mant, London)*
09:30	Safety signals in Phase I as triggers for go/no-go decision in further development *(Georg Wensing, Wuppertal)*
10:00	Coffee Break
10:30	**Parallel workshops:** • *Minimising risk by optimising clinical trial design and performance (Wolfgang Timmer, Mannheim)* • *Experience with and options for microdosing studies (Berend Oosterhuis, Zuidlaren; Andreas Kovar, Darmstadt)* • *Practical aspects of clinical trials with challenge agents (Hermann Fuder, Hamburg)* • *Burn-out and work-life balance (in German) (Wolfgang Seifert, Berlin; Katharina Erb-Zohar, Hanau)*
12:00	Coffee Break

Session V — **Human Pharmacology for Biologicals**

	Chair: Christian Hinze, Ingrid Klingmann
12:10	Relationship between CMC and toxicology in the development of biologicals *(Stefan W. Hockertz, Seelze)*
12:40	Clinical development programmes for biosimilars *(Hildegard Sourgens, Munich)*
13:10	Specific challenges in human pharmacology trials with biologicals *(Wolfgang Greb, Neuss)*
13:40	Closing Remarks *(Gerd Mikus)*
13:45	Farewell lunch