DAY 2 12 APRIL 2013

Session 4: Innovative approaches to Proof-of-Concept

Chairs: J. Taubel, London (UK)
O. van Schoor, Antwerp (Belgium)

9:00	Rapid transition from bench to bedside: An overview; what is new, what has proven its value, what are the latest trends in translational medicine *J. Theis, Bergisch-Gladbach (Germany)*
9:30	Network-based drug discovery – rationale and successful application to epilepsy *M. Johnson, London (UK)*
10:00	Cutting edge developments: biomarker qualification as an indicator for clinical endpoints and their role in setting an optimal biologic dose *S. Jurcevic, London (UK)*
10:30	Break

11:00	Parallel Workshops
WS1-WS4	Repetition of Day 1
WS1	Cardiac safety, QT assessment *B. Mendzelevski, London (UK)* *J. Taubel, London (UK)*
WS2	PK/PD modeling *R. Gomeni, La Fouillade (France)*
WS3	Application of Bayesian Statistics in early development studies *P. Sanwald Ducray, Basel (Switzerland)* *F. Vandenhende, Genappe (Belgium)*
WS4	Adaptive study design in early phase clinical research *M. O'Kane, London (UK)* *U. Lorch, London (UK)*
WS5.b	Pain Models *Ph. Danjou, Paris (France)*
12:30	Lunch Break

Session 5: Strengthening European Human Pharmacology for the Early Development of New Medicines

Chairs: P. Dewland, Cardiff (UK)
H. Sourgens, Munich (Germany)

13:30	Open Forum Discussions: A critical review of the proposed EU Clinical Trial regulation *W. Janssens, Brussel (Belgium)* *Federal Agency for Medicine and Health Products*
14:15	Need for a uniform European registration system for volunteer participation? *A. Peremans, Aalst (Belgium)*
15:00	Risk adapted approaches and clinical trial notification scheme *M. O'Kane, London (UK)*
15:45	Closing remarks by Club Phase I
16:00	End of Conference

Venue:
Hotel Sophia Country
3550 Route des Dolines BP 15
06410 Biot-Sophia Antipolis (FRANCE)
Phone: +33 4 92 966878

Inquiries:
Intercom Kongresse GmbH
Antje Blömeke | Matthias Runow
Eppendorfer Baum 39a
20249 Hamburg (GERMANY)
Phone/-Telefax: +49 40 480610 -62/ -66
abloemeke@intercom.de | mrunow@intercom.de

Fees:

Member of*	380 €
Non-Members	430 €
Junior Scientist	270 €

*CP1: http://www.clubphase1.com
*AGAH: http://www.agah.info
*BAPU: http://www.bapu.be
*AHPPI: http://www.ahppi.org.uk

Start Online-Registration and Hotel reservation by:
http://l.hh.de/JointConference_2013

CLUB PHASE 1

Joint Conference of European Human Pharmacological Societies

EARLY CLINICAL UTILITY ASSESSMENT OF NEW MEDICINES IN DEVELOPMENT

Photo: Marcus Augustine

11 & 12 April 2013

Nice Sophia Antipolis, FRANCE

3rd Announcement

Dear Colleague

2013 is a special year for CLUB PHASE 1, as this year it celebrates its 20th anniversary, welcoming fellow European colleagues of AGAH, BAPU and AHPPI to the stunning region of NICE, where we will join forces to offer our second joint meeting.

It will be a great opportunity to share our views on the challenges currently being faced by the Early Clinical Development and Clinical Pharmacology.

The meeting will focus on Early Clinical Utility Assessment of new medicines and how early development should be conducted to optimize the challenging process of reaching efficient and early go/no go decisions.

After review of some "historical" cases, this meeting will update attendees on new translational tools and innovative approaches, and will highlight the need for a strong presence of European Human Pharmacology in Early Development.

We hope that the plenary lectures and workshops will provide ample opportunity to discuss ideas, strategies, methods, technology and experience in early clinical development.

Looking forward to welcoming you in Sophia Antipolis, France.

Doctor Yves Donazzolo
Club Phase 1 President

DAY 1 11 April 2013

08:00 Registration

08:30 Welcome and introduction to the Joint Conference of Club Phase I, AGAH, BAPU and AHPPI

Session 1: Lessons learned from late phase failures and successes

Chairs: *Y. Donazzolo, Grenoble (France)*
M. Raghoebar, Antwerp (Belgium)

8:45 Lessons learned from Rimonabant and other CB1 blockers: did we try to crack a nut with a sledgehammer?
R. F. Witkamp, Wageningen (The Netherlands)

9:15 Clinical Pharmacology and Clinical Utility of Abiraterone Acetate
E. Mannaert, Beerse (Belgium)

9:45 The role of Phase I in the quest for "good" cholesterol – failure of the CETP modulator Dalcetrapib
M. Derks, Basel (Switzerland)

10:15 Break

Session 2: New translational tools and methodologies

Chairs: *A. Patat, Rennes (France)*
M. Hammond, Slough, Berkshire (UK)

10:45 Usefulness of modeling and simulations in drug development
E. Pigeolet, Basel (Switzerland)

11:15 Pharmacometrics: a new tool for optimizing early drug development in oncology
R. Gomeni, La Fouillade (France)

11:45 New biomarkers for drug-induced liver injury: first² insights from clinical quantification
M. Merz, Basel (Switzerland)

12:15 Quantification of EEG: pre-competitive consortium on the use of EEG as a CNS biomarker
Ph. Danjou, Paris (France)

12:45 Lunch Break

14:15 Parallel Workshops

WS1 Cardiac safety, QT assessment
B. Mendzelevski, London (UK)
J. Taubel, London (UK)

WS2 PK/PD modeling
R. Gomeni, La Fouillade (France)

WS3 Application of Bayesian Statistics in early development studies
P. Sanwald Ducray, Basel (Switzerland)
F. Vandenhende, Genappe (Belgium)

WS4 Adaptive study design in early phase clinical research
M. O'Kane, London (UK)
U. Lorch, London (UK)

WS5.a Suicidality assessment
E. Legangneux, Basel (Switzerland)

15:45 Break

Session 3: Training and education in early clinical drug development

Chairs: *K. Breithaupt-Grögler, Frankfurt (Germany)*
J. de Hoon, Leuven (Belgium)

16:15 European post-graduate training in pharmaceutical medicine and drug development
I. Klingmann, Brussels (Belgium)

16:35 Human Pharmacology courses: the UK experience
J. Posner, London (UK)

16:55 Open Forum Discussion: "Diploma-level training for Phase 1 Investigators – need or nice-to-have?"

17:15 End of Sessions on Day 1

19:30 Scientific Conference Dinner