International Workshop on
New Regulatory Requirements and Current Scientific Aspects on the Preclinical and Clinical Investigation of Drug-Drug Interactions

Marbach Castle, Lake Constance, Germany

May 30th - June 1st 2010

The present Note for Guidance for the Investigation of Drug Interactions by the European Agency for the Evaluation of Medicinal Products (EMEA) was issued in the nineties. Over the last decade, however, considerable knowledge has been gained about underlying mechanisms of drug-drug interactions (DDIs) and the applied methodologies for the investigation of DDI potential and extrapolation of outcomes to other drug combinations knowing that investigating all permutation of various drug combinations is unrealistic. To integrate current knowledge, the EMEA is currently revising its DDI Note for Guidance document to update several areas, and the revised draft Guideline will be published for public consultation in 2010.

The meeting "New Regulatory Requirements and Current Scientific Aspects on the Preclinical and Clinical Investigation of Drug-Drug Interactions" will combine a regulatory update on the investigation of DDIs from the European perspective with a scientific update on the investigation of DDIs. Four sessions comprising a 'regulatory update', 'metabolic drug-drug interactions (mDDI)', 'non-metabolic DDIs & PGx of DDIs', and 'tools in design & evaluation of DDI-trials for better timing of DDI-trials in course of clinical development' will address the latest knowledge and strategies in this key area of drug development. Commonalities and differences between US and EU regulatory requirements in conducting DDI studies will also be addressed.

The topics will be covered by international experts from European regulatory authorities, pharmaceutical companies/consultancies and academia. The program will provide a unique opportunity to learn about the European perspective on the investigation of drug interaction and to gain a better understanding on 'which studies are needed when?', and 'how these should be performed / interpreted?'.

The meeting will be held in Marbach Castle, located on the beautiful surrounding of the Western shore of Lake Constance within a 45 min distance to Zurich International Airport (see the following web site: www.schlossmarbach.de).

Meeting Organizers:

- Hartmut Derendorf, PhD FCP; *College of Pharmacy, University of Florida, USA*
- Robert Hermann, MD FCP; *cr.appliance, Germany*
- Amin Rostami-Hodjegan, PhD FCP; *Faculty of Medical and Human Sciences, University of Manchester, UK*
- Oliver von Richter, PhD FCP; *Dept. Exploratory Medicine, Merck Serono* Germany;

Invited Speakers:

Uwe Fuhr, MD; *Clinical Pharmacology, University of Cologne, Germany*

Isabelle Ragueneau-Majlessi; *Clinical Pharmacology, University of Washington, USA*

Supporting Professional Organisations:

The meeting is supported by the following professional organisations :

- Association for Applied Human Pharmacology (AGAH)
- American College of Clinical Pharmacology (ACCP)
- BioLAGO – The international Life Science Network in the Lake Constance Region

Internationaler Workshop

New Regulatory Requirements and Current Scientific Aspects on the Preclinical and Clinical Investigation of Drug-Drug Interactions

Schloß Marbach, Bodensee

30. Mai - 1. Juni 2010

Die noch gültigen EMEA Guidelines zur Untersuchung von Arzneimittelwechselwirkungen stammen aus den 90er Jahren. Neue, bedeutende Erkenntnisse zu verschiedenen Mechanismen von Arzneimittelwechselwirkungen sind im vergangenen Jahrzehnt gewonnen worden, wohl wissend, dass nicht alle Variationen von Arzneimittel-Interaktionen untersucht werden können.

Die EMEA überarbeitet derzeit diese Guidelines und eine neue Fassung soll 2010 publiziert werden.

Der internationale Workshop « New Regulatory Requirements and Current Scientific Aspects on the Preclinical and Clinical Investigation of Drug-Drug Interactions » kombiniert die Überarbeitung der Guidelines mit einem wissenschaftlichen Update bei der Untersuchung von Arzneimittelwechselwirkungen. In 4 Sitzungen werden die neuesten Erkenntnisse und Strategien auf verschiedenen Arbeitsgebieten behandelt :

- Regulatory Update
- Metabolic Drug-Drug Interactions (mDDIs)
- Non-metabolic DDIs & PGx of DDIs
- Tools in Design & Evaluation of DDT-trials for better timing of DDI-trials in course of clinical development

Die Gemeinsamkeiten und Unterschiede zwischen US und EU Zulassungen werden ebenfalls aufgezeigt.

International anerkannte Experten von Zulassungsbehörden, Pharmazeutischer Industrie, Beratungsunternehmen und aus der Wissenschaft werden im Workshop mitwirken. Damit haben die Teilnehmer die außergewöhnliche Möglichkeit die Anforderungen an die Untersuchung von Arzneimittelwechselwirkungen aus europäischer Perspektive besser zu verstehen.

Der Workshop findet im Schloß Marbach statt, das am westlichen Bodensee liegt und in 45 Minuten vom Internationalen Flughafen Zürich aus zu erreichen ist.

Organisatoren des Workshops sind Hartmut Derendorf, Robert Hermann, Amin Rostami-Hodjegan und Oliver von Richter. Unterstützt wird die Veranstaltung von der AGAH (Association for Applied Human Pharmacology), ACCP (American College of Clinical Pharmacology), DMDG (Drug Metabolism Discussion Group) und BioLAGO.

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