

Oncology

DGRA-Memberworkshop September 13, 2011

Wissenschaftszentrum Bonn,

Ahrstraße 45, 53175 Bonn

10.00 a.m. – 4.30 p.m.

Moderation: Dr. Christine Mayer-Nicolai, DGRA Vice Chair
Dr. Ulrich Granzer, DGRA Chair

Speakers: **Prof. Dr. Lothar Bergmann**, Uni-Klinikum Frankfurt, Oncology Dept.
Dr. Bertil Jonsson, MPA Medical Products Agency
Dr. Jan Müller-Berghaus, PEI Federal Paul-Ehrlich-Institute
Dr. Otmar Pfaff, Merck Serono Head Global Reg. Affairs Oncology
Devices
Dr. Christoph Unkrig, BfArM Federal Institute for Drugs and Medical

Programme:

- 10.00 a.m. I. 15-years EMA experience in Oncology: Guidance – Products – Endpoints**
- Current body of EMA Guidance and future evolution. Revised Guidance “Evaluation of anticancer medicinal products in man” (2011) including appendixes on ‘Methodological issues related to progression-free survival’ (2008), ‘Haematological malignancies’ (2010) and addendum on ‘Paediatric oncology’ (2004). ‘Note for Guidance on non-clinical evaluation for anticancer pharmaceuticals’ (ICH S9) (2010)
 - EMA experience with oncology drugs 1995-2011: trends and shifts. ‘Personalized medicines’ in oncology – myth or reality?
 - EMA viewpoint on the use of surrogate endpoints in the cancer setting. Will ‘targeted therapies’ impact on EMA’s viewpoint?

Dr. Bertil Jonsson, MPA

10:45 – 11:15 coffee break

- 11:15** **II. Assessment of new applications and type II variations in the cancer setting: The Regulators' experience**
- Beyond the Common Technical Document: Avoiding pitfalls in Art 8.3 and type II variation dossiers for cancer products
 - CMC aspects and patterns regarding type I variations for marketed oncology products: do they work like other medicinal products?
 - Risk-benefit assessment of oncology products: any particularities in the evaluation of cancer medicines?
- Dr. Christoph Unkrig, BfArM*

- 11.45** **III. Highly innovative medicinal products: how to successfully develop biologicals in oncology**
- 'State-of-the-art' assessment of immunogenicity for innovative biologicals
 - Specific considerations for the early clinical testing – did the 2007 Guideline for 'first-in-man clinical trials for potential high-risk medicinal products' deliver?
- Dr. Jan Müller-Berghaus, PEI*

12:30- 1.30 **lunch break**

- 1.30** **IV. Global development of new cancer medicines: achievements, hurdles and gaps in the regulatory framework**
- Product approval patterns in the EU and US and Japan: similar, but not identical
 - Achievements, hurdles and unfilled gaps in the regulatory harmonization of oncology drug product development
 - Developing personalized medicines globally: lessons to learn how to integrate emerging regions into the clinical development
- Dr. Otmar Pfaff, Merck Serono*

2.15 **coffee break**

- 2.45** **V. Pre-and post-approval studies in hematology and oncology: The Investigator's perspective**
- Prof. Dr. Lothar Bergmann, University Hospital Frankfurt*

ca. 3.30 **VI. Concluding discussion of the panel**
all speakers and participants

further information

p.t.o.

Date:

Tuesday, September 13, 2011

Start: 10.00 a.m.

End: around 4:30 p.m.

Venue:

Wissenschaftszentrum Bonn, Ahrstraße 45,
D-53175 Bonn, phone: +49 228/302-0

Participation fees:

For DGRA members and M.D.R.A. students
course XII: €250

The Casino is open for lunch (not included)

Cancellation terms:

Up to two weeks before the first day of the
conference(30-Aug-11): €50; up to one week
before the first day of the conference (6-Sep-11):
50% of fee; late cancellations: full conference
fee if a substitute participant (DGRA member)
cannot be put forward.

In the event of cancellation by the organizer, any
fees already paid will be fully reimbursed.

Conference language:

English

Room reservation:

A limited number of rooms are available for
participants at special rates in the hotels listed
below. When making reservations(up to August
15) please refer to DGRA.

- Hotel Bristol, Bonn-Innenstadt
Phone: +49 - 228/269 88 49
- Hotel Stern, Bonn-Innenstadt
Phone: +49 - 228 /72 67 0

More available rooms for direct booking
www.bonnhotels.de (incl. public transport),
www.hrs.de

Registration:

DGRA members are requested to use the form at
www.dgra.de or contact us at info@dgra.de

DGRA-office
Schedestraße 9
D-53113 Bonn
Fax: +49 228/368 26 47
E-mail: info@dgra.de