

Therapeutic Vaccines

DGRA-Memberworkshop November 27, 2012

Wissenschaftszentrum Bonn,
Ahrstraße 45, 53175 Bonn

10.00 a.m. – 4.30 p.m.

Moderation: Dr. Bettina Klug

Speakers: Dr. Bridget Heelan, MHRA, London
Dr. Matthias Giese, IMV Heidelberg
Dr. Nathalie Morgensztejn, ANSM France
Dr. MD Patrick Therasse, GlaxoSmithKline Biologicals
Prof. Dr. Jürgen Rockstroh, Uniklinik Bonn
Dr. Matthias Schroff, Mologen AG, Berlin

Programme:

10.00 a.m. **I. Breaking tolerance, pre-requisite for the development of therapeutic vaccines - new approaches in vaccine development.**

How we meet regulatory requirements

Point out the immunological challenge with therapeutic vaccines

- “autologous” antigen – breaking tolerance
- Autoimmunity
- Role of innate immune response
- Role of cellular immune response

Immune modulators

- Own platform technology

Dr. Matthias Schroff, Mologen AG

10.45 – 11.15 coffee break

**11.15 a.m. II. Approved veterinary vaccines paving the way for the development of human therapeutic vaccines?
Current status of approved therapeutic vaccines in the veterinary field**

Equine Arteritis Virus-Vaccine

- Disease characteristic and vaccine design
- Impact for human medicine

Canine Melanoma Vaccine

- Biology of canine melanoma
- The vaccine
- Impact for human medicines

Dr. Matthias Giese, Institute for Molecular Vaccines

**12.00 III. Clinical development of therapeutic cancer vaccines
▪ Clinical development of a human anticancer vaccine
(Presentation will be tailored upon the request)**

PhD MD Patrick Therasse, Vice President GlaxoSmithKline Biologicals

12.45- 1.45 p.m. lunch break

**1.45 IV. Challenges in the clinical development of cancer vaccines –
Regulators perspective**

Translation from non-clinical to clinical data-what are the challenges

- Impact of the natural course of the disease on the clinical development
- What can we expect from a tumour vaccine

Clinical trials (EMA and FDA guidelines)

- Patients populations
- Endpoints

Dr. Bridget Heelan, MHRA

2.30 – 3.00 p.m. coffee break

3.00 – 3.45 V. HIV Therapeutic Vaccine Shows Signs of Promise

▪ Vacc-4X

- Objectives of a therapeutic HIV vaccines
- Preliminary Results (presented in Bangkok)

Prof. Dr. Jürgen Rockstroh, Uniklinik Bonn

**3.45 – 4.30 VI. The place of a therapeutic HIC vaccine in the toolbox
for HIV treatments**

- Goals to archive with the vaccine
- Safety and efficacy requirements
- Clinical trial issues ~ how to select the clinical trial population

Dr. Nathalie Morgensztejn, National Agency of Medicine and Health Product Safety

further information

p.t.o.

Date:

Tuesday, November 27, 2012

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 XIV: € 220

The Casino is open for lunch (not included)

Cancellation terms:

Up to two weeks before the first day of the
conference (13-Nov-12): € 50; up to one week
before the first day of the conference (20-Nov-
12): 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 Nov 9)
please refer to DGRA.

- Sternhotel, Bonn-Innenstadt
Phone: +49 - 228/7 26 70
- Villa Godesberg, Bonn-Bad Godesberg
Phone: +49 - 228/83 00 60

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

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