9th Open EIP Scientific Symposium

And

Final ABIRISK Open conference

on

Immunogenicity of Biopharmaceuticals

Draft Program

13-16 November 2017

Altis Hotel

Lisbon, Portugal
Monday 13th November 2017

EIP Training Course

10:00 Validation of ADA Assays - Recent experience and issues
    Arno Kromminga, IPM Biotech/BioAgilytix, Germany
    Daniel Kramer, Sanofi, Germany

12:30 Lunch

14:00 Immunogenicity – Regulatory Issues
    Paul Chamberlain, France
    Joao Pedras-Vasconcelos, FDA, USA

ABIRISK closed meeting

11:00 ABIRISK steering committee meeting

12:30 Lunch

14:30 ABIRISK General Assembly
Tuesday 14th November 2017

09:00 Welcome and Introduction by the EIP Chairman and ABIRISK coordinators

09:15 Keynote lecture: Title: to be determined
Amy Rosenberg, FDA, USA

Session 1: Regulatory Aspects

10:00 Regulatory Aspects of the Immunogenicity Assessment of Biosimilars
Paul Chamberlain, France

10:30 Status draft FDA guideline
Joao Pedras-Vasconcelos, FDA, USA

11:00 Coffee Break

11:30 Novel Aspects of the latest EMA immunogenicity guideline
Pekka Kurki, Finland

12:00 FDA 2016 Immunogenicity Guidance – Experience I
Madeleine Dahlbäck, Novo Nordisk, Denmark

12:30 FDA 2016 Immunogenicity Guidance – Experience II
Szilard Kamondi, Roche, Germany

13:00 Panel Discussion

13:30 Lunch

Session 2: New insights into pharmacokinetics and ADA determination for biologics

15:00 Combination of ADA levels determination and pharmacokinetic parameters for determination of immunogenicity
Denis Mulleman, CNRS, France

15:30 Simultaneous characterization ADAs using combination of immune capture and LC-MS approaches
Gilles Miscoria, Sanofi, France
16:00  Immunogenicity of a bi-functional molecule in the clinics - what can be learned from a sophisticated assay battery
N.N.

16:30  Coffee break

17:00  Production and characterization of human ADA as references for ADA assays
Luca Piccoli, IRB, Switzerland
Louis Christodolou, UCB Pharma, UK

17:30  New insights in determination of ADA for interferon beta and Natalizumab in multiple sclerosis
Florian Deisenhammer, Austria
Anna Fogdell-Hahn, Sweden

19:00  Dinner
Wednesday 15th November 2017

9:00  Keynote lecture: Immunotoxicity of Biologics
      Marc Pallardy, INSERM, France

Session 3: Immunogenicity and clinical outcomes

09:45  Influence of bio-clinical variables on the immunogenicity
       Signe Hassler, INSERM, France

10:15  Results from the ABIRISK multiple sclerosis retrospective cohort
       N.N.

10:45  Coffee break

11:15  Results from the ABIRISK Hemophilia retrospective cohort
       Delphine Bachelet, INSERM, France

11:45  Influence of ADA on the clinical effectiveness of biologics in inflammatory
diseases: data from the prospective ABIRISK cohort
       Xavier Mariette or Matthieu Allez and Philippe Broet, INSERM, France

12:30  Lunch

Session 4: Predictive tools for immunogenicity and Genetic analysis

14:00  Predictive analysis for immunogenicity
       Philippe Broet, INSERM, France

14:30  Genetic factors influencing the development of binding and neutralizing
       antibodies against interferon beta treatment in MS patients
       Till Andlauer, Germany

15:00  Highly reproducible, sensitive and early detection and characterization of
       antidrug responses using RNA-seq
       Niek de Vries, AMC, The Netherlands

15:30  Coffee break

Session 6: Mechanisms of immunogenicity and biomarkers - part I

16:00  Immunophenotyping as a predictive marker of immunogenicity- Overall
       strategy
Liz Jury, UCL, UK

16:30  Immunophenotyping and B cells and B reg cells in Rheumatoid arthritis
      Claudia Mauri, UCL, UK

17:00  Immunophenotyping as a predictive marker of immunogenicity in multiple sclerosis
      Marsilio Adriani, UCL, UK

**Session 7: Social event**

19:00  Get together
Thursday 16th November 2017

8:00   Keynote lecture: “Title: to be determined”
       Alessandro Sette, UCSD, USA

Session 8: Mechanisms of immunogenicity and biomarkers - part II

08:45  Role of T-cells in immunogenicity of biologics in Intestinal Bowel disease
       Enrico Maggi, Italy

09:15  Interaction between Methotrexate and BAFF for preventing immunogenicity of
       biologics
       Xavier Mariette, INSERM, France

09:45  Title to be determined
       Sebastien Lacroix-Desmazes, CNRS, France

10:15  Coffee break

Session 9: Prediction tool evaluation and validation efforts

10:45  Comparison of T cell assays: results from the ABIRISK consortium
       Sebastian Spindeldreher, Novartis, Switzerland

11:15  In vitro prediction of immunogenicity and link with the clinic
       Bernard Maillere, CEA, France

11:45  Impact of aggregates on DC maturation and antigen presentation antigen
       N.N.

12:15  AAPS perspective on predictive assays
       Vibha Jawa, Merck, USA

12:45  Impact of innate immune response modulating impurities on product
       immunogenicity
       N.N.

12:45  Lunch

Session 10: Immunogenicity of new scaffolds

13:45  Immunogenicity and what about the targets
Wibkle Lembke, Covagen, Switzerland

14:15 Immunogenicity CAR-T cells
Fraser McBlane, Novartis, Switzerland

Session 11: Outlook

14:45 The legacy of ABIRISK, outlook and future perspectives
N.N.

15:00 Future Challenges of Immunogenicity
N.N.

15:45 End of conference