Program of EBF Focus Workshop "**Today's challenges and solutions in assessing immunogenicity in patients**"

September 19-20, 2018.
Lisbon, Portugal

19/sep/2018

08.45 – 09.00	**Welcome and aim of the meeting**
09:00 – 12.30	**Harmonized approaches for immunogenicity method validation**
09:00 – 09:25	Introduction to the session - Overview of current global regulations *Jo Goodman, on behalf of the EBF*
09:25 – 09:50	Harmonisation of immunogenicity testing : The EU perspective *Meenu Wadhwa (National Institute for Biological Standards and Control)*
09:50 - 10:10	Case Study: Request for a full tiered approach assay validation for a well-known drug used for a new indication – when clinical experience was not sufficient *Anna Laurén, Wieslab/Eurodiagnostics*
10:10 – 10:50	**Coffee break & networking**
10:50 – 11:10	Analytical scientists and the statisticians collaborate to make the right decision for cut-points *Alexandra Hawes, LGC*
11:10 – 11:30	Practical solutions to outlier decisions, pre-existing and treatment-boosted ADA and low biological variability *Viswanath Devanarayan, Charles River*
11:30 – 11:50	Experiences with different cut-point approaches in clinical immunogenicity testing *Szilard Kamondi, Roche*
11:50 – 12:30	Panel discussion *Moderator: Robert Nelson. Panelists: Viswanath Devanarayan, Jo Goodman, Meenu Wadha, FDA representative (approval pending)*
12:30 – 13:40	**Lunch**
13:40 – 15:00	**Harmonized approaches for immunogenicity method validation - cntd**
13:40 – 14:00	Effect of different approaches on perceived assay sensitivity and drug tolerance – sense and nonsense of positive controls *David Egging, Synthon Biopharmaceuticals BV*
14:00 – 14:20	Feedback on EBF immunogenicity harmonisation activities *Jo Goodman, on behalf of EBF*
14:20 – 14:40	AAPS-sponsored ADA Validation Testing and Reporting Harmonization

Meina Liang, on behalf of the AAPS community

14:40 – 15:00 Panel discussion

Moderator: Michaela Golob. Panel: Meina Liang, Shobha Purushothama, Jo Goodman, Robert Nelson

15:00 – 15:40 Tea break & Networking

15:40 – 17:30 Progress in Clinical nAb assays

15:40 – 15:50 Introduction to the session

James Munday, on behalf of the EBF

15:50 – 16:10 Integration of PK-PD-ADA data for assessment of immunogenicity impact

Robert Nelson, Novimmune

16:10 – 16:30 Developing neutralising assays – challenging molecules and challenging requirements

Carina de Lemos Rieper, Novo Nordisk

16:30 – 16:50 Inferring Neutralising Antibodies – When data integration is appropriate?

Shobha Purushothama, Biogen

16:50 – 17:30 Q&A

17:30 End of Day 1

<u>20/sep/2018</u>

08:45 – 09:00 Introduction to day 2

09:00 – 12:00 Clinical immunogenicity and the value for the patient and physician

09:00 – 09:20 Introduction to the session

Michaela Golob, on behalf of the EBF

09:20 – 09:40 Clinical relevance of unwanted drug-induced immune responses

Arno Kromminga, BioAgylitix

09:40 – 10:00 Considerations of immunogenicity assessment at different clinical phases

Kate Peng, Genentech

10:00 – 10:20 Evaluation of clinical impact of immunogenicity and its challenges

Veerle Snoeck, UCB

10:20 – 11:00 Coffee Break & networking

11:00 – 11:30 After 20 Years of immunogenicity testing, where do we stand today

Daniel Kramer, Sanofi

11:30 – 12:00 Taking the “false” out of ADA testing results: towards better interpretation of clinical relevance

Lorin Roskos, MedImmune

12:00 – 13:15 Lunch

13:15 – 14:30 Panel discussion – Clinical immunogenicity and the value for the patient and physician

13:15 – 13:30 Introduction to the closing panel discussion

Jo Goodman, on behalf of the EBF

13:30 – 14:30 Panel discussion

Moderator: Jo Goodman. Panel: Lorin Roskos, Venke Skibeli (Norwegian Medicines Agency, member of the Biosimilar Medicinal product Working Party (BMWP), Robert Nelson and Daniel Kramer.

14:30 – 15:00 Summary, conclusion and next steps

15:00 – 16:00 Closing Tea break and adjourn