October 5, 2017

11:00-12:00 Registration

12:00-13:00 László Endrényi: Scientific factors in biosimilar product development

13:00-14:00 Lunch break

14:00-15:00 Helmut Schütz: Open issues in the assessment of bioequivalence and biosimilarity.

Main topics:

- Unequal carry-over – "solved" in BE but still an Issue in Assessing Biosimilarity?
- Multi-Group and Multi-Site Studies. To pool or not to pool?
- Group-Sequential and Two-Stage Designs.
- Reference-scaling and Control of the Type I Error.

14:00-15:00 Course

15:00-15:20 Coffee break

15:20-16:20 Course

16:20-16:40 Coffee break

16:40-17:40 Course

17:40-18:00 Discussion

October 6, 2017

9:00-9:30 Registration (for those attending only day 2)

9:30-10:00 Johanna Mielke: Clinical trials for biosimilars in Europe: an updated systematic comparison of the clinical development programs

10:00-10:30 Tóthfalusi László, László Endrényi: Algorithms for evaluating reference scaled average bioequivalence: power, bias and consumer risk

10:30-11:00 Bernd Jilma: Investigating PK/PD in the steep ascending part of the dose response curve

11:00-11:30 Coffee Break

11:30-12:20 Keynote lecture 1. Andrea Laslop: 12 years of biosimilars in Europe: what's the exposure and response in our learning curve?

12:20-12:50 Ina-Christine Rondak, Stephan Lehr: Regulatory perspective on comparison of quality attributes in drug development

12:50-13:45 Lunch Break

13:45-14:25 Keynote Lecture II. János Szebeni: Immune side effects of biologicals and nanomedicines: unsolved issues in bio- and nanosimilar development.

14:25-14:45 Coffee Break

14:45-16:45 Round table discussion

Moderator: Júlia Singer (Chief Scientific Officer, Accelsiors Ltd)

Discussants:

Regulatory perspective: Stephan Lehr (Biostatistician, Austrian Medicines and Medical Devices Agency)

Industry perspective: Heike Wöhling (Head of Biostatistics, Sandoz Biopharmaceuticals)

Panel members

Ildikó Aradi (Head of Clinical Development of Biologics, Gedeon Richter Plc., Vice-Chair, European Generic Medicines Association - European Biosimilars Group)

Bernd Jilma (Vice Chair, Department Clinical Pharmacology, Medical University of Vienna)

Franz König (Associate Professor, Medical Unversity of Vienna, Section for Medical Statistics)

Andrea Laslop (Unit Head, Austrian Medicines and Medical Devices Agency)

Johanna Mielke (Biostatistician, Novartis Pharma AG)

Vid Stanulovic (Consultant, Clinical Development and Pharmacovigilance)