Title: 1st Annual Biosimilars Forum

Date: 6 – 7 October 2016

Accelsiors CRO - Háros Street 103, Budapest 1222, Hungary

Organisers: Hungarian Society for Clinical Biostatistics, Vienna Biometrical Society, Accelsiors Ltd.

Registration form:

http://www.accelsiors.com/wp-content/uploads/Biosimilar-form.pdf

Registration deadline:

25 September, 2016

Detailed Agenda

October 6, 2016

13:00-14:00 **Registration**

14:00-15:00 **Lecture 1: Assessing Biosimilarity: Issues and Recent Development**

- **Fundamental differences**
  - Generics versus biosimilars
- **Regulatory requirements**
  - EU EMA, US FDA, and WHO
- **Definition of biosimilarity**
  - US BPCI Act
- **Scientific factors for assessing biosimilarity**
  - Criteria for biosimilarity
  - Non-inferiority vs. equivalence
  - Multiple reference products
- **Development of biosimilarity index**
  - Unified and robust approach
- **Concluding remarks**

15:00-15:30 **Coffee Break**

15:30-16:30 **Lecture 2: Assessing Interchangeability: Issues, Designs, and Statistical methods**

- **Concept of interchangeability**
  - Switching
  - Alternating
- **Current issues**
  - Produce same clinical results in any given patient
- **Criteria for interchangeability**
  - Adjust for variability of reference product
- **Study designs**
  - Switching designs
- **Statistical methods**
- **Concluding remarks**

16:30-17:00 **Coffee Break**

17:00-18:00 **Lecture 3: Analytical Similarity Assessment in Biosimilar Studies**

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17:00-18:00

- **Background**
  - o BPCI's definition of biosimilarity
  - o FDA's guidances on biosimilars
  - o Recent regulatory submission
- **Analytical similarity assessment**
  - o Classification of critical quality attributes (CQAs)
  - o Tiered approach
- ☒ **Equivalence test for Tier 1 CQAs**
- ☒ **Quality range approach for Tier 2 CQAs**
- ☒ **Raw data and graphical comparison for Tier 3 CQAs**
- **US FDA's current thinking on Tiered approach**

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9:30-10:00 **Registration (for those attending only day 2)**

10:00-10:30 **Keynote lecture**
László Endrényi, László Tóthfalusi: Interchangeability of biological drug products

10:30-10:50 **Johanna Mielke, Bernd Jilma, Franz Koenig, Byron Jones:** Clinical trials for authorised biosimilars in the European Union: A systematic review

10:50-11:10 **Stephan Lehr:** Biosimilar development - a statistical assessor's perspective

11:10-11:30 **Coffee Break**

11:30-11:50 **Andrea Laslop:**The regulator's view on the totality of evidence for biosimilars

11:50-12:10 **Julia Singer:** The intention to treat principle and imputation of missing data in clinical studies for biosimilars

12:10-12:30 **Vid Stanulovic:** Demonstrating similarity of clinical safety

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12:30-12:50	**Martin Wolfsegger: Evaluation of different methods to establish biosimilarity on the quality attributes level**
12:50-13:45	**Lunch**
13:45-15:45	**Round table discussion**
Moderator:	**Ildikó Aradi** (Head of Clinical Development of Biologics, Gedeon Richter Plc.,Vice-Chair, European Generic medicines Association - European Biosimilars Group)
Panel Members:	**Péter Arányi** (Secretary, Medical Research Council, Ethics Committee for Clinical Pharmacology)
	Andrea Laslop (Unit Head, Austrian Medicines and Medical Devices Agency)
	Stephan Lehr (Biostatistician, Austrian Medicines and Medical Devices Agency)
	Franz König (Associate Professor, Medical Unversity of Vienna, Section for Medical Statistics) - tbc
	Johanna Mielke (Biostatistician, Novartis Pharma AG)
	Julia Singer (Chief Scientific Officer, Accelsiors Ltd)
	Vid Stanulovic (Consultant, Clinical Development and Pharmacovigilance)
	Martin Wolfsegger (Associate Director, Shire)
	Heike Wöhling (Head of Biostatistics, Sandoz Biopharmaceuticals)