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**

# October 6, 2016

**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**

# October 7, 2016

**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

# October 7, 2016

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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) |