

Scientific Program

4th International Conference and Exhibition on

Biologics and Biosimilars

October 26-28, 2015 Baltimore, USA



Conference Series LLC Ltd

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Scientific Program

Day 1 October 26, 2015

09:00-09:45 Registrations

Harbor Room

conferenceseries LLC Ltd 09:45-09:55

Opening Ceremony

Keynote Forum

- 09:55-10:00 **Introduction**
- 10:00-10:30 **Patrick Lucy**
Pfenex Inc., USA
- 10:30-11:00 **Kamali Chance**
Quintiles, USA

Networking & Refreshments 11:00-11:15 @ Foyer

- 11:15-11:45 **Christopher J Leintz**
Pfizer Inc., USA
- 11:45-12:15 **Mark A Emalfarb**
Dyadic International Inc., USA

Group Photo

Track 1: Challenges and Regulatory Approach for Biosimilars

Track 2: Emerging Biosimilars in Therapeutics

Track 4: Emerging Biologics in Therapeutics

Track 13: Current Challenges in Advancement of Biologics

Session Chair: Patrick Lucy, Pfenex Inc., USA

Session Co-Chair: Jill A Myers, Momenta Pharmaceuticals, USA

Session Introduction

12:20-12:40 **Exploring government pricing and reimbursement policy challenges associated with biosimilars**

William A Sarraille, Sidley Austin LLP, USA

12:40-13:00 **The economic viability of a U.S. biosimilars industry**

Alex Brill, Matrix Global Advisors, USA

Lunch Break 13:00-13:45 @ Eden's Landing Restaurant

13:45-14:05 **Challenges and approaches in demonstrating biosimilarity at the physicochemical and biological level**

Jill A Myers, Momenta Pharmaceuticals, USA

14:05-14:25 **Clearing the path for market entry before the USPTO**

Y Jenny Chen, Wolf Greenfield & Sacks, PC, USA

14:25-14:45 **Similar biologics in India – legal and regulatory perspective**

Milind Antani, Nishith Desai Associates, India

14:45-15:05 **US biosimilars taking flight: Discussion of the key events and cases shaping the US biosimilar landscape**

Timothy J Shea, Sterne Kessler Goldstein & Fox PLLC, USA

15:05-15:25 **Biosimilars market access and penetration in the Obama care era –considerations for providers, payers, prescribers and patients**

Gary C Cupit, Somnus Therapeutics, USA

Networking & Refreshments 15:25-15:40 @ Foyer

15:40-16:00 **U.S. biosimilars – The courts interpret BCPIA steps**

Denise M Kettelberger, Sunstein Kann Murphy & Timbers LLP, USA

16:00-16:20 **AVX-470, an Orally-Delivered GI-Targeted anti-TNF Biobetter**

Neil L Schauer, Avaxia Biologics, USA

16:20-16:40 **Challenges of the recombinant pharmaceutical biosimilar proteins expression and enhanced refolded recovery from E.coli**

Vivek Kumar Morya, Inha University, Republic of Korea

16:40-17:00 **Emerging biosimilar in therapeutics: Where we are and what is future?**

Dipti Gulati, PJI Biotech, USA

Panel Discussion 17:00-17:20

Networking and Cocktail sponsored by Covance 17:30-19:00

Harbor Room

Keynote Forum

- 10:00-10:30 **Sarfaraz K Niazi**
Therapeutic Proteins International, USA
- 10:30-11:00 **Angela Furlanetto**
Dimock Stratton LLP, Canada

Networking & Refreshments 11:00-11:15 @ Foyer

- Track 3: Clinical Studies and Clinicians Prospects for Biosimilars
- Track 5: Globalization of Biosimilars
- Track 12: Regulatory Affairs and Intellectual Property Rights
- Track 14: Biosimilar Companies and Market Analysis

Session Chair: Ronald A Rader, Biotechnology Information Institute, USA
 Session Co-Chair: Lisa V Mueller, Michael Best & Friedrich LLP, USA

Session Introduction

- 11:15-11:35 **Impact of the biosimilars pipeline and nomenclature on market development**
Ronald A Rader, Biotechnology Information Institute, USA
- 11:35-11:55 **Evolution of the global biosimilars market: Lessons learned**
Raymond A Huml, Quintiles Inc., USA
- 11:55-12:15 **Biosimilars: Is the risk worth the reward**
James Harris III, Healthcare Economics LLC, USA
- 12:15-12:35 **Biosimilar Companies and Market Development Worldwide**
Lisa V Mueller, Michael Best & Friedrich LLP, USA
- 12:35-12:55 **Patent eligibility challenges to biologics under America Invents Act (AIA) and Myriad**
Raj S Davé, Pillsbury Winthrop Shaw Pittman LLP, USA

Lunch Break 12:55-13:40 @ Eden's Landing Restaurant

- 13:40-14:00 **Cost- Effective clinical trial design to detect immunogenicity and efficacy differences between biosimilar and innovator product.**
Candida Fratazzi, BBCR Consulting, USA
- 14:00-14:20 **Janssen Biotech V. Celltrion: The balance between the BPCIA and litigation**
Kerisha A Bowen, Dentons US LLC, USA
- 14:20-14:40 **Issues in the clinical development of the first wave of biosimilars**
Nigel Rulewski, Quintiles, USA
- 14:40-15:00 **Supplementary protection certificates (SPCs) in Europe – What is the 'basic patent' and what is the 'product'?**
Tom Carver, Wragge Lawrence Graham & Co, UK

Networking & Refreshments 15:00-15:15 @ Foyer

- Track 6: Biosimilars Innovator Pharmaceutical Products
- 8: Bioequivalence Assessment

Session Chair: Roman T Drews, LFB, USA
 Session Co-Chair: Min Zhang, Fujifilm Diosynth Biotechnologies, USA

Session Introduction

- 15:15-15:35 **CMC consideration for biosimilar drug development and manufacturing process**
Marcus Mreyen, Protagen Protein Services, Germany
- 15:35-15:55 **Overcome challenges to manufacture of biosimilars through media/feed screening and cell culture process optimization**
Min Zhang, Fujifilm Diosynth Biotechnologies, U.S.A
- 15:55-16:15 **Erbix biosimilar**
Alan L Epstein, USC Keck School Of Medicine, USA
- 16:15-16:35 **Production of biosimilar MAbs in transgenic animals– Opportunities and challenges**
Roman T Drews, LFB, USA

Poster Presentation

- PC-001 **Identification and quantification of flavonoids and their glycosides for quality assessment of Terminalia species applying liquid chromatography hyphenated with mass spectrometric techniques**
Awantika Singh, Central Drug Research Institute, India
- PC-002 **TBA**
Chuck Morrison, Proteome Sciences, USA
- PC-003 **Patients Satisfaction on Antiretroviral Therapy Monitoring Laboratory Services in public Hospitals, Addis Ababa, Ethiopia.**
Tedla Mindaye, Addis Ababa University, Ethiopia
- PC-004 **Improving injection force of high viscous drugs by a unique, commercially available needle created by using tapered technology**
Mitsuru Takahashi, Terumo Medical Corporation, USA

- PC-005 **Structural Modification of the Alpha-helical Antimicrobial Brevinin-2 Related Peptide – A Comparison Study of Biosimilars**
Siqin Liu, Queen's University Belfast, UK
- PC-006 **Ultra performance liquid chromatography mass spectrometric analysis for rapid quantitation of isoquinoline alkaloids in Thalictum reniforme**
Vikas Bajpai, Central Drug Research Institute, India
- PC-007 **Cold active endo-glucanase from Antarctic Yeast, Glaciozyma antarctica P112; expression and characterisation**
Salimeh Mohammadi, University Kebangsaan Malaysia, Malaysia

Day 3 October 28, 2015

Harbor Room

Track 7: Biosimilars Analytical Strategies
Track 9: BCS & IVIVC Based Biowaivers
Track 10: Plant Produced Biosimilar Products
Track 11: Pharmacovigilance and its Challenges

Session Chair: Mario DiPaola, Bluestream Lab., USA

Session Co-Chair: Mariana Babayeva, Touro College of Pharmacy, USA

Session Introduction

09:30-10:15 Workshop on A review of the how state regulators are dealing with biosimilars. a case study of the Maryland policy debate and legislation

Gene M Ransom III, University of Maryland and University of Baltimore School of Law, USA

10:15-10:35 Safety and biosimilarity of ior®EPOCIM compared to Eprex® based on toxicologic, pharmacodynamic and pharmacokinetic studies in the Sprague-Dawley rat

Gordon T Bolger, Nucro-Technics, Canada

Networking & Refreshments 10:35-10:50 @ Foyer

10:50-11:10 Prevention potency of soaps and disinfectants on Vancomycin resistant Enterococcus faecalis infection

Adetunji Olawale, Osun State Polytechnic, Nigeria

11:10-11:30 Bioanalytical challenges of biosimilar development; making you wish you had a mirror to put in front of the innovator drug

Afshin Safavi, BioAgilytix, USA

11:30-11:50 Protein binding drug-drug interaction

Mariana Babayeva, Touro College of Pharmacy, USA

11:50-12:10 The characterisation of biosimilar mAbs using biologically relevant and sensitive ADCC methodologies

Andy Upsall, BioOutsource, UK

12:10-12:30 Development of a biosimilar CMC strategy for the identification of critical quality attributes

Samantha Little, Covance Laboratories, UK

12:30-12:50 Characterization of Glatiramer acetate C-terminal heterogeneity

Mario DiPaola, Bluestream Lab., USA

Lunch Break: 12:50-13:35 @ Eden's Landing Restaurant

Closing & Award ceremony

Bookmark your dates

5th European Biosimilars Congress

June 27-29, 2016 Valencia, Spain

<http://biosimilars-biologics.pharmaceuticalconferences.com/europe/>

6th International Conference and Exhibition on

Biologics & Biosimilars

October 20-22, 2016 Houston, USA

<http://biosimilars-biologics.pharmaceuticalconferences.com/>