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OMICS Group Conferences
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Email: biosimilars2013@omicsonline.net
Day 1  September 23, 2013

08:00-09:00  Registrations

09:00-09:25  Opening Ceremony

09:25-09:30  Introduction
Michael Retsky  Harvard School of Public Health, USA

09:30-09:55  Challenges and Regulatory Approach for Biosimilars
Session Chair: Jichao (Jay) Kang, Laureate Biopharmaceutical Services, USA
Session Co-Chair: Kevin W. McCabe, Sterne, Kessler, Goldstein & Fox, USA

11:00-11:20  Strategy for biosimilar development
Jichao (Jay) Kang, Laureate Biopharmaceutical Services, USA

11:20-11:40  The need for a reference product database for biosimilars
Jeff Lyons, Absorption Systems, USA

11:40-12:00  Freedom to operate issues and patent litigation considerations for biosimilars
Sailesh Patel, Schiff Hardin LLP, USA

12:00-12:20  Clearing the biosimilar patent thicket with IPRs
Kevin W. McCabe, Sterne, Kessler, Goldstein & Fox, USA

12:20-12:40  Integrated strategy for biosimilar development: A multidisciplinary approach for risk reduction
Adriana E. Manzi, Atheln Inc, USA

12:40-13:35  Lunch Break @ Oak

Zaina Qureshi, University of South Carolina, USA

13:55-14:15  Compliance and thoughtfulness from idea to commercial production
Deborah Thibodeaux, DKT Lab Consulting, USA

14:15-14:35  Complexities of biosimilar product
Alok Bandypadhyay, Design Space Inpharmatics, USA

14:35-14:55  Biosimilar in pharmerging markets
Jun Wang, Duke University School of Medicine, USA

14:55-15:15  Analytical characterization of biosimilar products to establish biosimilarity
Fiona Greer, SOS M-Scan, UK

15:15-15:35  Challenges in demonstrating biosimilarity and interchangeability of biosimilar products
Radeina Challand, PRA International, UK

15:35-15:50  Coffee Break @ Oak

15:50-16:10  Power without a patent: Twelve-year biologics data exclusivity period & a totality of the evidence standard for biosimilarity
Jonathan Stroud, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, USA

16:10-16:30  Patent issues for biologic and biosimilar products
William Simmons, Sughrue Mion PLLC, USA

16:30-16:50  The relevance of immunogenicity in preclinical development
Ciriaco Maraschiello, Harlan Laboratories Inc., USA

16:50-17:10  The data of the head-to-head use of two biosimilars of beta-interferon-1b in MS therapy at the Moscow MS Center
Ekaterina Popova, Moscow Multiple Sclerosis Center, Russia

17:10-17:30  Post-approval safe harbor…or not?
Brian R. Dorn, Barnes & Thornburg LLP, USA

17:50-18:50  Cocktails Sponsored by Journal of Bioanalysis & Biomedicine @ Oak
Day 2  September 24, 2013
Magnolia
Keynote Forum

09:30-09:55  Arturo Solis Herrera
Human Photosynthesis Study Center, Mexico

09:55-10:20  Leandro Mieravilla
Cassara Biotech, Canada

Track 2: Emerging Biosimilars in Therapeutics
Session Chair: Russell Reeve, Quintiles Inc, USA
Session Co-Chair: Subhash Basu, University of Notre Dame, USA

Session Introduction

10:20-10:40  Development and manufacturing of a biobetter therapeutic: A case study
Michiel E. Ultee, Laureate Biopharmaceutical Services, Inc., USA

10:40-11:00  Development and manufacturing of a biobetter therapeutic: A case study
Kent Pryor, ZZ Biotech, USA

Coffee Break 11:00-11:15 @ Oak

11:15-11:35  Use of apoptosis assays as tools to compare biosimilarities of anticancer drugs or agents
Subhash Basu, University of Notre Dame, USA

11:35-11:55  Alpha ENaC-b as a gene therapy in salt-sensitive hypertension
Marlene Fouad Shehata, Marlene Shehata Pharmaceuticals, Canada

11:55-12:15  Reverting antibiotic tolerance of bacterial persisters by a brominated furanone, (Z)-4-bromo-3-(bromomethylene)-3-methylfuran-2(5H)-one
Jiachuan Pan, Syracuse University, USA

12:15-12:35  Comprehensive functional & biological characterization of biosimilar monoclonal antibodies
Daniel Galbraith, BioOutsourc Ltd, UK

Lunch Break 12:35-13:30 @ Oak

13:30-13:50  Some possibilities in trial design to reduce sample size
Russell Reeve, Quintiles Inc., USA

13:50-14:10  Current analytical techniques for characterization of carbohydrate biosimilars
Parastoo Azadi, University of Georgia, USA

Track 3: Clinical Studies and Clinicians Prospects for Biosimilars
Track 4: Globalization of Biosimilars
Session Chair: Leandro Mieravilla, Cassara Biotech, Canada
Session Co-Chair: Jennifer Campbell, Merck Millipore, France

Session Introduction

14:10-14:30  Accelerating biosimilars mabs to market: A predefined process coupled with consultative services
Jennifer Campbell, Merck Millipore, France

14:30-14:50  Publication planning for biosimilars
Paul Lane, UBC- Envision Group, UK

14:50-15:10  Commercialization considerations for biosimilars
Steven Lehrer, Optimal Strategix Group, USA

15:10-15:30  Successful commercialization of biosimilars in Europe 1 market authorization, 27 markets
Marguerite Mensenrose-Harsme, Medac GmbH, Germany

Coffee Break 15:30-15:45 @ Oak

15:45-16:05  Biosimilar market: Business development overview
Leandro Mieravilla, Cassara Biotech, Canada

16:05-16:25  Use of cardiac glycosides for inhibition of C-creative protein and treatment of atherosclerosis -Road map to clinical applications
Oliver Zimmermann, Cardiovascular Center Oberallgau-Kempten, Germany

16:25-16:45  Biosimilars: Less than a decade and a new paradigm already?
Stephanie C. Finnegan, BioRASI, USA

16:45-17:05  Pharmacokinetics of venlafaxine and its major metabolite o- desmethylvenlafaxine in freely moving mice using automated dosing/sampling system
Bijay Aryal, Chitwan Medical College Pvt Ltd, India

Poster Presentations

17:00-18:00  Cocktails Sponsored by Journal of Bioequivalence & Bioavailability @ Oak

Day 3  September 25, 2013
Magnolia

Track 6: Analytical Strategies
Session Chair: Michael Retsky, Harvard School of Public Health, USA
Session Co-Chair: Yunsheng Hsieh, Protech Pharmaservices Corporation, Taiwan

Session Introduction

09:30-09:50  Comparability study to support upstream and downstream process development
Rong-Rong Zhu, EMD Millipore, USA

09:50-10:10  How long should adjuvant chemotherapy be given?
Michael Retsky, Harvard School of Public Health, USA

09:10-10:30  Biosimilar characterization and comparability assessments experiences from a CRO GMP Protein chemistry laboratory
Leonard Bell, Covance Laboratories, UK

Coffee Break 10:30-10:45 @ Oak
10:45-11:05 Robust, streamlined 2-D western blot workflow for evaluation of antibodies developed for detection of host cell proteins (HCP)
Sricharan Bandhakavi, Bio-Rad Laboratories, USA

11:05-11:25 The use of high-speed liquid chromatography/Tandem mass spectrometry in the GLP assays for biosimilars
Yunsheng Hsieh, Protech Pharmaservices Corporation, Taiwan

11:25-11:45 Silicon photonic bio-sensing, a new technology for immunogenicity testing
Martin Gleeson, Genalyte, USA

11:45-12:05 The use of mass spectroscopy in the GMP analysis of biosimilars
Mario DiPaola, Blue Stream Laboratories Inc., USA

Track 5: Biosimilars Innovator Pharmaceutical Products
Track 7: Bioequivalence Assessment
Track 8: BCS & IVIVC Based Biowaivers

Session Chair: Ajay K. Banga, Mercer University, USA
Session Co-Chair: Hu Yan, Zhengzhou University, China

Session Introduction

12:05-12:25 Host cell protein characterization for bioprocess and product improvement
Rong-Rong Zhu, EMD Millipore, USA

12:25-12:45 Novel pharmacologic and phenotypic methods to characterize carrier-mediated and nanoparticle agents as part of preclinical and clinical development
William Zamboni, University of North Carolina, USA

Lunch Break 12:45-13:30 @ Oak

13:30-13:50 Applications of microchip-CE for high throughput screening of protein quality
Bahram Fathollahi, PerkinElmer, USA

13:50-14:10 Human photosynthesis: a turning point in the understanding and treatment of Alzheimer’s Disease
Arturo Solis Herrera, Human Photosynthesis Study Center, Mexico

14:10-14:30 Human skin as an in vitro surrogate model for bioequivalence comparison of topicals
Ajay K. Banga, Mercer University, USA

14:30-14:50 PNIPAM hydrogels and PLGA nanoparticles: Applications in drug delivery systems
Hu Yan, Zhengzhou University, China

14:50-15:10 Antioxidative and anticholinesterase compounds from two closely related Croton species
Ashwell Ndhlala, University of KwaZulu-Natal, South Africa

15:10-15:30 B-PAPM- Biological potency of certain antifeedant plant extracts against some pathogens for the management of human disease
S. Abideen, Dr. Zakir Hussain College, India

Award Ceremony

Coffee Break 15:30-15:45 @ Oak