14-15 November 2016
Congress Center Basel, Switzerland

Early confirmed speakers include:

Adam Kautzner, Vice President, Formulary & Drug Trends Solutions, Express Scripts
Alain Beck, Senior Director Analytical Chemistry, CIPF and Associate Editor, mAbs
Bernd Liedert, Sr.Clinical Program Leader Biosimilars, Boehringer Ingelheim
Brian Edwards, Principal Consultant, NDA Regulatory Science
Cecil Nick, Vice President, Biotechnology, PAREXEL
Gianluca Trifirò, Assistant Professor of Pharmacology, Erasmus Medical Center
Joanna Brougher, Biotech, Pharma and Medical Device IP and Corporate Counsel; Adjunct Lecturer, Harvard School of Public Health
Mark McCamish, Head of Global Biopharmaceutical & Oncology Injectables Development, Sandoz
Michael Reilly, Executive Director, Alliance for Safe Biologic Medicines
Morgane Beck, Pharmacist, OMEDIT Alsace, Agence Régionale de Santé Alsace
Mourad Farouk, Global Head Medical Affairs Biosimilars, Biogen
Ruediger Jankowsky, Managing Director, Cinfa Biotech GmbH
Paul Chrisp, Programme Director, Medicines and Prescribing Centre, NICE
Pierre Michetti, Gastroenterologist, Centre Hospitalier Universitaire Vaudois
Steffen Thirstrup, Director, NDA Regulatory Advisory Board, NDA Advisory Services
Steinar Madsen, Medical Director, Department of Drug Information, Norwegian Medicines Agency
Tim Shea, Director, Sterne, Kessler, Goldstein & Fox
Tom Gregson, Business Development Specialist, Myoderm
Tony Williams, General Manager, TWC Pharma Consulting
Uwe Gudat, Head of Safety, Biosimilars, Merck

Invited speakers include:

Biosimilar developers:
Amul Agrawal, Vice President of International Operations, Torrent Pharmaceuticals Ltd
Amy Pott, VP, Global Patient Access, Baxalta, Inc.
Bert Liang, CEO, Pfenex and Chairman, Biosimilars Council
Chad Pettit, Executive Director, Global Value and Access for the Amgen Biosimilars Business, Amgen
Craig Wheeler, President and CEO, Momenta Pharmaceuticals
Dagmar Rosa-Björkeson, Executive Vice President and President, Biosimilars, Baxalta
Dmitry Morozov, Chief Executive Officer, Biocad
Edric Engert, Senior Vice President, Biosimilars, Teva Pharmaceuticals
Eduardo Cioppi, Quality Operations and Regulatory Affairs Director, Amega Biotech
Felix Siegel, Director Regualtory Affairs, Biosimilars, Boehringer Ingelheim
Geoffrey Eich, Executive Director, Innovation, Amgen
Haiqiong Montalta-He, Senior Manager Global Regulatory Affair Biosimilars, Mylan
Ira Jacobs, Global Oncology Lead, Biosimilars, Pfizer
Kiran Mazumdar Shaw, Chairperson and Managing Director, Biocon
Liz Pollitt, Vice President, Head of CMC, Regulatory Affairs, Celltrion
Matt Eddleston, Director, Global Health & Value, Pfizer
Michael Franken, President, Biosimilars Business, Momenta Pharmaceuticals
Nicole Quon, Head of Global Payer Marketing & Market Development, Global Market Access Biosimilars, Boehringer Ingelheim
Nils Peter Debus, Head Business Development Biosimilars, Boehringer Ingelheim
Peter Stenico, Head Biopharmaceuticals and Oncology Injectables, Western Europe, Sandoz (Novartis)

Philip Ball, Executive Director, Biologics Policy and Strategy, **Actavis/Allergan**
Rajiv Malik, President, **Mylan**
Sean Harper, Senior Vice President, Clinical Development and Clinical Medical Officer, **Amgen**
Sethu Madhavan, Manufacturing Head- Biosimilars and Insulins, **Biocon**
Simon Sturge, Senior Vice President, Head of Biosimilars & COO, Merck Healthcare, **Merck**
Tim Fratus, Executive Director, U.S. Marketing, Biosimilars, **MSD**
Vijay Maheshwari, Senior Executive - Regulatory Affairs (Biosimilars), **Intas Pharmaceuticals**

Regulators, Payers and Investment Professionals:
Alexandre Moreau, Director, Oncology Directorate, **ANSM (France)**
Ann Johnsson, Senior Expert, **Medical Products Agency (Sweden)**
Asbjørn Mack, Health Economic Advisor, **Legemiddelinnkjøpssamarbeidet (LIS) – Drug Procurement Cooperation**
Elena Wolff-Holz, Medical Assessor, **Paul Ehrlich Institute (Germany)**
Jian Wang, Division Chief, Clinical Evaluation Division, Biologics and Genetic Therapies Directorate, **Health Canada**
Martina Weise, Head, Unit on Diabetes/Cardiovascular Disorders, **Federal Institute for Drugs and Medical Devices (Germany)**
Sol Ruiz, Head of Sector, Biotechnology and Advanced Therapies, **Spanish Medicines Agency**
Thijs Giezen, External Assessor, **Medicines Evaluation Board (Netherlands)**

Clinicians, Academia, Industry Groups & Patient Groups:
Allyson Pollock, Professor of Public Health Research and Policy; Director, Global Public Health Unit, **Queen Mary University**
Antonio Ciaglia, Research & Policy Manager, **International Alliance of Patients' Organizations**
Fraser Cummings, Gastroenterologist, **University Hospital Southampton National Health Service Foundation Trust**
Huub Schellekens, Professor, Departments of Pharmaceutical Sciences and Innovation Studies, **Utrecht University**
Jorgen Jahnsen, Professor of Gastroenterology, **University of Oslo**
Peter Taylor, Norman Collisson Professor of Musculoskeletal Sciences, **University of Oxford**
Theo Dingermann, Senior Professor, Institute for Pharmaceutical Biology, **Goethe University**

Monday 14 November 2016	
08:00 08.45	Registration opens Conference doors opens
09:00	Opening remarks **Miss Hannah Yates**, Conference Manager, **World Biosimilar Congress 2016**
09:10	Chair's opening remarks **Steffen Thirstrup**, Director, NDA Regulatory Advisory Board, **NDA Advisory Services** (Confirmed)
BIOSIMILAR DEVELOPMENT FOR GLOBAL HEALTHCARE SYSTEMS	
09:20	**Biosimilars uptake and market considerations in the EU** • Gain a better understanding of the observations and key learnings from Biogen's experiences • Hear a case study on the NHS adoption programme • How do Biogen's experiences in the EU differ from the rest of the world? **Mourad Farouk, Global Head Medical Affairs Biosimilars, Biogen** (Confirmed)
09:40	**Critical quality attributes and extrapolation** • Best practices to enable an abbreviated clinical programme based on the analytical characterisation and closeness of the biosimilar molecule to the originator • Navigating global regulatory pathways with regards to critical quality attributes and extrapolation • Clinical relevance of product quality attributes **Mark McCamish**, Head of Global Biopharmaceutical & Oncology Injectables Development, **Sandoz** (Confirmed)
10:00	**Latest developments with the Norwegian study and the uptake of biosimilars in clinical practice** • Hear the latest from the biosimilar studies coming out of Norway • How has the data enabled the uptake, from a healthcare perspective? • Lessons learnt from Norway that can be applied elsewhere to encourage greater uptake of biosimilars globally? **Steinar Madsen,** Medical Director, Department of Drug Information, **Norwegian Medicines Agency** (Confirmed)
10:20	*Reserved for a platinum sponsor*
10:40	*Networking refreshment break*
11:40	**A holistic approach to technical and clinical development of biosimilars** • Gain an understanding as to why technical development is key to biosimilar development and why it should be considered way before clinical development • How do you then translate the technical findings to the clinical level? • Best practices in implementing this concept to detect differences and enable appropriate product attributes **Ruediger Jankowsky**, Managing Director, **Cinfa Biotech GmbH** (Confirmed)
12:00	**Post-market assessment of biosimilars** • Hear first-hand experience of evaluating the use and benefit-risk profile of biosimilars through an Italian healthcare database network • What have been some of the challenges to do with data sources and methodology? • What can be learnt on the effects of switching from this research? **Gianluca Trifirò,** Assistant Professor of Pharmacology, **Erasmus Medical Center** (Confirmed)
12:20	Speed Networking, sponsored by **Myoderm**

12:40	**Tom Gregson,** Business Development Specialist, **Myoderm** (Confirmed)
13:00	*Networking lunch break*
14:30	**Development considerations: Comparing major markets including US, EU, Japan and China** • Hear different approaches to similarity of quality attributes • Gain an understanding of navigating different clinical data requirements and their endpoints • What are the requirements for choice of reference product, interchangeability, ethnicity and need for data from local patients, meeting with regulators and conducting global studies? **Cecil Nick**, Vice President, Biotechnology, **PAREXEL** (Confirmed)
PRICING DEBATE	
14:50	**Panel: Pricing Debate** • Are biosimilars cost effective? • What economic aspects need to be reviewed when it comes to biosimilars versus reference biologics? • Lessons learnt from existing biosimilar approvals, both in the EU and the USA as well as in emerging markets, especially in terms of pricing and sustainability of the market • What can biosimilar developers do to ensure favourable economics of their biosimilars during development? • What are the incentives to switch? **Adam Kautzner,** Vice President, Formulary & Drug Trends Solutions, **Express Scripts** (Confirmed)
15:45	*Networking refreshment break*
CLINICAL RELEVANCE AND EXTRAPOLATION	
16:30	**Real world applications of extrapolation and the current state of interchangeability** • Gain an understanding of the real world applications of extrapolation, with regards to immunogenicity and efficacy of extrapolation • Review some recently published, established data on the topic • Updates on the topic of interchangeability and the effect it is having on the industry's ability to design clinical trial to fulfil global guidelines **Bernd Liedert,** Sr.Clinical Program Leader Biosimilars, **Boehringer Ingelheim** (Confirmed)
16:50	**Case Study: NICE widens access of biosimilars to patients in England and Wales** • Gain an understanding of NICE's approach to biosimilars • What can be learnt from their recent recommendations in terms of the way they are approaching biosimilar approval and clinical use, including their views on patient involvement? • Where does NICE stand on the topic of extrapolation? **Paul Chrisp,** Programme Director, Medicines and Prescribing Centre**, NICE** (Confirmed)
17:10	**Analytical perspective of biosimilar development: Equivalence to the originator** • How do you best overcome the challenge that the regulators want statistics to justify equivalence, through reviewing particular product attributes, but that the originator has changed over time and is no longer equivalent to itself? • What does this mean to how the market is evolving to enable abbreviated clinical programmes based on the analytical characterisation and closeness of the molecule to the originator? • Keep up to date with the latest analytical technology *Reserved for a supporting partner*
17:30	**Panel: The 'Indication Extrapolation Conundrum'**

	• Following the USA's first biosimilar approval, what do we know about international practices regarding extrapolation? • How can biosimilar developers best approach this challenge given different regulators are reviewing data differently, with different views on what is clinically meaningful? • How does the notion of interchangeability affect the ongoing topic of extrapolation? **Bernd Liedert,** Sr.Clinical Program Leader Biosimilars, **Boehringer Ingelheim** (Confirmed) **Cecil Nick,** Vice President, Biotechnology, **PAREXEL** (Confirmed)
18:10	*End of Day 1 – Networking drinks reception*

Tuesday 15 November 2016				
08:00 08.55	Registration opens Conference doors opens			
09:00	Recap of Day 1 and opening remarks for Day 2 **Tony Williams**, General Manager, **TWC Pharma Consulting** (Confirmed)			
CMC, PRECLINICAL AND CLINICAL CONSIDERATIONS FOR BIOSIMILARS				
09:05	**Is there a role for modelling and simulation in biosimilars development?** • Using modelling and simulation for clinical trial design • Are models / simulations useful educational tools? • What can modelling and simulation tell us about the emerging safety profile? **Uwe Gudat**, Head of Safety, Biosimilars, **Merck** (Confirmed)			
09:25	**Tailor-made design of biosimilar clinical trials** • Gain an understanding of the key attributes of an effective clinical trial design for biosimilars? • How does this design differ across the globe? • What considerations need to be taken into account when working across different indication areas? *Reserved for a supporting partner*			
09:45	**Experiences in ensuring your biosimilar meets quality/CMC criteria globally** • Lessons learnt having achieved biosimilar approval • Best practices in navigating global regulatory pathways from a quality and CMC perspective • Biosimilars toward 2020: What can we expect? *Reserved for a supporting partner*			
10:05	**Multilevel state-of the art analytical methods for mAbs and Fc-fusion proteins biosimilarity assessment** • Insights of emerging 2D-LC-MS and HDX-MS methods • Orthogonal chromatographic and electrophoretic methods hyphenated to Mass Spec • FDA/EMA approved mAbs and biosimilars case studies **Alain Beck,** Senior Director Analytical Chemistry, **CIPF** and Associate Editor, **mAbs** (Confirmed)			
10:25	*Networking refreshment break*			
Roundtables: GLOBAL SUCCESS STORIES				
11:25	*Hear success stories from industry and academia on developing and commercialising biosimilars on a global scale. There will be 2 rotations of 35 minutes allowing you to attend discussions on the 2 most pertinent topics for your business.*			
	Biosimilars in France **Morgane Beck,** Pharmacist, OMEDIT Alsace, **Agence Régionale de Santé Alsace** (Confirmed)	Biosimilars in Russia	Biosimilars in Spain	Biosimilars in India
12:40	*Networking lunch break*			
IMPLEMENTING BIOSIMILARS INTO THE MARKET				
14:20	**The regulators guide to biosimilars** • What are their views on clinically meaningful differences/clinical relevance and how to overcome the challenges associated with biosimilar development? • Will complete interchangeability ever be a reality?			

	• How do regulators view the acceptability of biosimilars?
14:40	**How has our understanding of the system to ensure safe use of biosimilars changed?** • Implications of treatment pathways for assessing individual benefit/risk of a product • State of readiness of healthcare technology for tracking biological products • Update about clinical implications of immunogenicity and how impact can be measured • Changing approach to regulatory requirements for risk management and what that means for biosimilars **Brian Edwards,** Principal Consultant, **NDA Regulatory Science** (Confirmed)
15:00	**A year to review: 2016, more decisions, more launches, more unanswered questions** • Hear how the year has played out from a legal perspective • What are we seeing from the US in terms of new decisions, new launches and their analysis of the data being submitted? • Incorporating IPRs into biosimilar litigation strategies • What impact is that having on the global biosimilar sector? **Tim Shea,** Director, **Sterne, Kessler, Goldstein & Fox** (Confirmed)
15:25	**Obtaining patent protection while operating in an "anti-patent" climate** • Overview of recent cases affecting the biotechnology industry • Impact on biosimilar development • Strategies for obtaining adequate patent protection **Joanna Brougher,** Biotech, Pharma and Medical Device IP and Corporate Counsel; Adjunct Lecturer, **Harvard School of Public Health** (Confirmed)
15:40	*Networking refreshment break*
16:30	**The clinician's guide to biosimilar implementation** • Gain an overview of a clinician's perspective on biosimilars in the gastroenterology setting • Views on switching patients from the originator to the biosimilar and examples of real life results in this area • Insights into a biosimilar registry being set up in Switzerland to monitor patients and pharmacovigilance and what this means for clinician perspectives on biosimilars globally **Pierre Michetti,** Gastroenterologist, **Centre Hospitalier Universitaire Vaudois** (Confirmed)
16:50	**Panel: What are the mechanics required behind the implementation of biosimilars in the market?** • How important is post-market surveillance to implementing biosimilars in the market in the first place? • Overview of the current situation pertaining to the global debate on naming of biosimilars • How has USA's first biosimilar approval contributed to the debate on naming? What can we expect to see with this ongoing debate as we move closer to 2020? • What role do collaborations and partnerships, including between academia and industry, play in the development of biosimilars? **Michael Reilly**, Executive Director, **Alliance for Safe Biologic Medicines** (Confirmed) **Pierre Michetti,** Gastroenterologist, **Centre Hospitalier Universitaire Vaudois** (Confirmed)
17:30	*End of Conference – Networking drinks reception*