FESTIVAL OF BIOLOGICS

Presents...

WORLD BIOSIMILAR CONGRESS EUROPE 2019

Basel Congress Centre, 15th-16th October 2019

Advisory board

Margaret (Maggie) Dolan, Associate Director Market Access Eu Biosimilars, **Biogen**
Alain Beck, Senior Director, Biologics CMC & developability, CIPF and Associate Editor, **mAbs**
Matthew Turner, Senior Director Government Affairs and Policy Biosimilars, **Fresenius**

Confirmed speakers

Pierre Bourdage, Global Head Sandoz Biopharmaceuticals**, Sandoz**
Alvin Luk, Senior Vice President & Chief Medical Officer, **Shanghai Henlius**
Wojciech Nowak, Public Affairs Director Central Eastern Europe, Russia, Central Asia, **Novartis**
Steinar Madsen, Medical Director**, Norwegian Medicines Agency**
Alastair Sayce, Head Biologics IP, **Teva**
Martin Perry, Consultant Physician & Rheumatologist, **NHS Greater Glasgow and Clyde**
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Margaret (Maggie) Dolan, Associate Director Market Access Eu Biosimilars, **Biogen**
Roman Drai, R&D Director, **GEROPHARM**
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Mourad Rezk, Executive Director, Global Head of Medical Affairs (Biosimilars), **Biogen**
Cecil Nick, Vice President, Biotechnology, **PAREXEL**
Annick de Vries, Director Bioanalysis, **Sanquin**
Jonathan Underhill, Medicines Clinical Adviser, Medicines and Technologies Programme (MTP), **NICE**
Magnus Bodin, Director Market Access, **Biogen**
Meenu Wadhwa, Section Leader for Cyotkines and Growth Factors Section, **NIBSC**
Aidan Fry, Editor, **Generics bulletin**
Andreu Soldevila, Chief Executive Officer (CEO), **Syna Therapeutics**
Tudor Arvinte, Chairman, CEO, **Therapeomic**
George Badescu, Vice President Scientific Affairs, **Heidelberg Pharma**
Hanmant Barkate, Vice President - Medical Services, **Glenmark Pharma**
Haleh Hamedifar, CEO, **Singapore Biotech Company**
Neil Hodson, EMENA Franchise Manager: Autoimmune and Fertility, **Accord Healthcare**
Kalveer Flora, Rheumatology Specialist Pharmacist, Deputy Chair, Rheumatology Pharmacists UK, Pharmacy Department, Northwick Park, **Central Middlesex and Ealing Hospital**
Richard Peck, Vice President/Regulatory Affairs, **Lupin Atlantis**
Kelly Burke, Senior Director Biologics, Europe, **Mylan and Medicines for Europe**
Tim Shea, Director **Sterne Kessler Goldstein and Fox Plc**
Andreas Herrmann, CEO, **Valerius Biopharma**
Steven Lehrer, Senior Management Advisor, **SBLehrer LLC**
Gustaf Befrits, Health Economist, **Stockholm County Council**
Rana Musa al-ali "Malkawi", Head of Clinical Studies, **Jordan FDA**
Sameer Awsare, Managing Director, **Kaiser Permanete**

Matthew Harman, Director of Pharmacy, **Employers Health**
Hanne Rolighed Christensen, Head of department, MD at Clinical Pharmacology Dept. **Bispebjerg Hospital**
Dorthe Bartels, Advisor, **Amgros I/S**
Uwe Gudat, Head of Clinical Safety & Pharmacovigilance**, Fresenius Kabi**
Arshad Jamil, Chief IP Counsel – Global Head IPR, **Biocon**
Philip Schneider, Chair, International Advisory Board, **Alliance for Safe Biologics Medicines**
Diego Rosselli, President, **ISPOR Colombia**
Andrew Spiegel, Executive Director, **Global Colon Cancer Association**
Chase Martin, Executive Director, **Global Alliance for Patient Access**
Corinna Sonderegger, Head, Device Portfolio, **Novartis**
Johnny Bane, Market Access Lead, **Sandoz**
Amgen representative TBA
Ted Mathias, Partner, **Axinn**
Stacie Ropka, Partner, **Axinn**
Sanjay Tiwari, Director, R&D, **Lupin**
Xin Zhang, Vice President, Global Clinical Operations and Affairs, **Shanghai Henlius Biotech**
Vasanti Natarajan, Head of Patient Value & Innovation (Europe), Global Medical Affairs**, Biocon Biologics**

Day 1 - Tuesday 15th October			
07:00	**Registration opens**		
08:30	**Conference doors open**		
	Opening Keynotes **Biosimilars in Europe** **ROOM: HELVETIA 1&2 (Swissotel)**		
09:00	**Welcome from Terrapinn**		
09:05	**Chair's opening remarks** **Margaret (Maggie) Dolan,** Associate Director Market Access Eu Biosimilars, **Biogen** (CONFIRMED)		
09:10	**Increasing biosimilar uptake: a multi-layered national approach** • National Strategies to improve uptake • How to engage clinicians and 'grassroots' healthcare professionals • Improving quality of care for patients who are prescribed biosimilars **Martin Perry,** Consultant Physician & Rheumatologist, **NHS Greater Glasgow and Clyde** (CONFIRMED)		
09:35	**Keynote panel discussion: a vision for biosimilar sustainability** • Overview of different initiatives and policies that may influence the uptake • What can be done to encourage sustainable biosimilar uptake in Europe? • Availability, pricing, reimbursement, demand-side policies, and recommendations to enhance uptake **Moderator: Margaret (Maggie) Dolan,** Associate Director Market Access Eu Biosimilars, **Biogen** (CONFIRMED) **Martin Perry,** Consultant Physician & Rheumatologist, **NHS Greater Glasgow and Clyde** (CONFIRMED) **Dorthe Bartels**, Advisor, **Amgros** (CONFIRMED) **Matthew Turner,** Senior Director Government Affairs and Policy Biosimilars, **Fresenius Kabi** (CONFIRMED) **Wojciech Nowak,** Public Affairs Director Central Eastern Europe, Russia, Central Asia, **Novartis** (CONFIRMED)		
10:30	**Networking break**		
11:20	**Roundtable discussion session** **ROOM: HELVETIA 1&2 (Swissotel)**		
	TABLE 1 **Biosimilar market access** **Margaret (Maggie) Dolan**, Associate Director Market Access EU Biosimilars, **Biogen** (CONFIRMED)	TABLE 2 **Biosimilar to biosimilar switching - opportunities and risks** **Johnny Bane,** Market Access Lead, **Sandoz** (CONFIRMED)	TABLE 3 **Hold or fold? Surviving a launch at risk** **Ted Mathias,** Partner, **Axinn** (CONFIRMED)
	TABLE 4 **Change of treatment guidelines for earlier use of Biologics** **Mareike Ostertag,** Director Science and Regulatory policy, **Novartis** (CONFIRMED)	TABLE 5 **The biosimilar introduction in Denmark** **Hanne Rolighed Christensen,** Head of department, MD at Clinical Pharmacology Dept. **Bispebjerg Hospital** **Dorthe Bartels**, Advisor, **Amgros**	TABLE 6 **Manufacturing** **Sanjay Tiwari,** Director, R&D, **Lupin** **Rustom Mody,** SVP, Head R&D, **Lupin**
12:35	**Networking lunch**		
12:45-13:30	**ROOM: RIO** **WORKSHOP: Characterisation of a biosimilar drug** **Tudor Arvinte,** Chairman, CEO, **Therapeomic** (CONFIRMED)		
	Track 1 **Commercialisation** **HELVETIA 1**	Track 2 **Development and Manufacturing of Biosimilars** **HELVETIA 2**	
	Chair: Steven Lehrer, Senior Management Advisor, **SBLehrer LLC**	**Chair:** TBC	
14:10	**Biosimilars in Europe after the 3 successful aTNF launches** • How the market developed since 2015 • Pivotal governmental initiatives • Important learnings to secure sustainable biosimilars market	**Protein misfolds: carrier of host cell proteins with potential risk of immunogenicity** • Misfolds are highly heterogenous in structure, function and the impurities they carry • Misfolds are linked to host cell proteins via covalent disulfide linkages	

	Magnus Bodin, Director Market Access, **Biogen** (CONFIRMED)	• Misfolds have scrambled intramolecular disulfide linkages.Can be folded to the native form by in-vitro addition of redox reagents **Rustom Mody,** SVP, Head R&D, **Lupin** (CONFIRMED)
14:30	**Commercialization of biosimilars** • Helping people around the world access high-quality medicine – together • Critical success factors and barriers **Florian Turk**, Global Head Commercial, Sandoz Biopharmaceuticals, **Sandoz** (CONFIRMED)	**Clinical development strategies for Biosimilars** • Biosimilar/ Similar Biologic—Concept & Historical Global development • Guidelines : EU, USA & Rest of the world • Clinical development : Challenges & Strategies • Marketing authorization of Biosimilar, Post-authorization data requirements • Interchangeability with biological reference product • Case studies of biosimilar development: from simple growth factor to complex monoclonal antibodies **Hanmant Barkate,** Vice President - Medical Services, **Glenmark Pharma** (CONFIRMED)
14:50	**The phenomenal uptake of biosimilars in Denmark. What's the secret?** • The uptake in Denmark of biosimilars has so far not only been very high but also extremely quick. No doubt this will also be the case for the next biosimilars on the verge of entering the market • A large number of stakeholders have played a very important part. Who are they, what are their respective roles and how exactly did each of them contribute to the result? • Is this only a success story or are there any clouds on the horizon? What can anybody learn from Denmark and what will prove more difficult to copy? Will the Danish market be sustainable in the coming years? **Dorthe Bartels**, Advisor, **Amgros I/S** (CONFIRMED)	**Insulin biosimilars development under changing environment** • Current landscape of biosimilars in Russia, • Approach to the development of insulin biosimilars in Russia, • 2 different regulatory requirements for development, which way to choose? • Research and development of insulin glargine biosimilar from scratch to Phase III clinical trials **Roman Drai,** R&D Director, **GEROPHARM** (CONFIRMED)
15:10	**The add challenges for Biosimilars in the retail market** • The market barriers that hinder the development of biosimilars at retail level • The Insulins example. Why competition is not working for Insulins? • The way forward. What can we do to increase competition? **Victor Lino Mendonça,** Head, Policy & Market Access Europe, **Mylan** (CONFIRMED)	**First approved biosimilar in China** • Current landscape of biosimilar development in China • China National Medicine Products Administration Regulatory Guideline • Clinical Development of China Rituximab Biosimilar **Xin Zhang,** Vice President, Global Clinical Operations and Affairs, **Shanghai Henlius Biotech** (CONFIRMED)
15:30	**Afternoon refreshments**	
15:45	**ROOM RIO** **WORKSHOP: Process control strategy for robust biosimilar manufacturing** • Process Variability • Process design for efficient control • Predictive modelling **Sanjay Tiwari,** Director, R&D, **Lupin** (CONFIRMED)	
	Commercialisation **HELVETIA 1**	**Development and Manufacturing of Biosimilars** **HELVETIA 2**
	Chair: Steven Lehrer, Senior Management Advisor, **SBLehrer LLC**	**Chair: TBC**
16:30	**Singapore biotech: a novel strategy in biosimilar market** • Biosimilar trends in none US markets • Biosimilars in APAC; Regulatory and Market Overview	**Arming biosimilar antibodies to produce biobetter therapeutics: Amanitin-based Antibody-Drug-Conjugates as new therapeutic modalities for cancer therapy**

	• Biosimilar regulation: recent major changes in highly regulated markets **Haleh Hamedifar**, CEO, **Singapore Biotech** (CONFIRMED)	• Antigen-Targeted Amanitin-Conjugates (ATACs) represent a new class of ADCs using the payload Amanitin • This payload introduces a novel mode of action into oncology therapy, the inhibition of RNA polymerase II. • The technology platform can be applied to biosimilar antibodies to arm them with additional MOAs to increase efficacy and provide new options in cancer therapy • Preclinical data of biobetter therapeutics based on biosimilar antibodies will be presented **George Badescu**, Vice President Scientific Affairs, **Heidelberg Pharma** (CONFIRMED)
16:50	**The integration of biosimilars in clinical practice** • What concerns do physicians, pharmacists & patients have regarding the use of biosimilars and how can we allay them • How much do stakeholders really know about biosimilars & how they are produced, their safety & efficacy • What data & educational needs are there • How can biosimilar companies instil confidence **Vasanti Natarajan**, Head of Patient Value & Innovation (Europe), Global Medical Affairs**, Biocon Biologics** (CONFIRMED)	**Biosimilars drug product and delivery device design and manufacturing: opportunities and points to consider** • Regulatory requirements and opportunities to differentiate • Understanding, predicting and aligning customer needs for a truly competitive product design • Fill & Finish Manufacturing for Biosimilars – technology & outsourcing considerations **Corinna Sonderegger,** Head, Device Portfolio, **Novartis** (CONFIRMED)
17:10	**Panel discussion: increasing global patient access** • How can industry work better with governments to increase patient access? **Moderator: Steven Lehrer,** Senior Management Advisor, **SBLehrer LLC** (CONFIRMED) **Victor Lino Mendonça,** Head, Policy & Market Access Europe**, Mylan** (CONFIRMED) **Mareike Ostertag,** Director Science and Regulatory policy, **Novartis** (CONFIRMED) **Philip Schneider,** Chair, International Advisory Board, **Alliance for Safe Biologics Medicines** **Chase Martin**, Executive Director, **Global Alliance for Patient Access** (COFIRMED)	17:10 **Cost effective development in Biosimilars: What is enough?** • Expression systems • Process development • Analytical development **Andreu Soldevila,** Chief Executive Officer (CEO), **Syna Therapeutics** (CONFIRMED) 17:30 **Going beyond biosimilars: the value of innovation and differentiation in biosimilars** • Biosimilars manufacturers face an increasing challenge to differentiate products in the market place • Describe how going beyond biosimilars to develop value-added products can give manufacturers a differentiated edge in a growing competitive space whilst simultaneously improving patient lives **Neil Hodson,** EMENA Franchise Manager: Autoimmune and Fertility, **Accord Healthcare**
17:50	Chair's end of day 1 remarks	Chair's end of day 1 remarks
18:00	**Offsite drinks reception**	

<table>
<tr><td colspan="3">Day 2 – Wednesday 16th October</td></tr>
<tr><td>08:00</td><td colspan="2">Registration opens</td></tr>
<tr><td>09:00</td><td colspan="2">Conference doors open</td></tr>
<tr><td></td><td colspan="2">Opening Keynotes
Biosimilars in the USA
HELVETIA 1&2</td></tr>
<tr><td>09:00</td><td colspan="2">Day 2 opening remarks
Chair: Steven Lehrer, Senior Management Advisor, SBLehrer LLC (CONFIRMED)</td></tr>
<tr><td>09:05</td><td colspan="2">The future of biosimilars in the US and European markets
• Importance of biosimilars: a key to sustainable healthcare future
• Differences between US and European markets: is the gap closing?
• Impact of biosimilars so far in Europe/US: the ongoing success story
• How to further improve the future of biosimilar access: incentivizing competition
Pierre Bourdage, Global Head Sandoz Biopharmaceuticals, Sandoz (CONFIRMED)</td></tr>
<tr><td>09:30</td><td colspan="2">Keynote panel discussion: Biosimilar market trends in the USA
• Is there a solution to the stagnation that biosimilar developers are facing in the US?
• Commercial challenges
• Regulatory issues – Interchangeability guidelines
• Who’s blocking biosimilar development and how can we tackle this?
Moderator: Steven Lehrer, Senior Management Advisor, SBLehrer LLC

Sameer Awsare, Managing Director, Kaiser Permanete (CONFIRMED)
Matthew Harman, Director of Pharmacy, Employers Health (CONFIRMED)
Andrew Spiegel, Executive Director, Global Colon Cancer Association (CONFIRMED)</td></tr>
<tr><td>10:20</td><td colspan="2">Networking break</td></tr>
<tr><td></td><td>Track 1
Guidelines, Safety and Regulation
HELVETIA 1</td><td>Track 2
Clinical Trials and Real-World Evidence
HELVETIA 2</td></tr>
<tr><td></td><td>Chair: Diego Rosselli, President, ISPOR Colombia (CONFIRMED)</td><td>Chair: Cecil Nick, Vice President, Biotechnology, PAREXEL (CONFIRMED)</td></tr>
<tr><td>11:25</td><td>Preparing a global regulatory strategy for a biosimilar product
• Establishing registration pathways in the EU, USA, ROW
• Accounting for regional differences
• How to communicate the regulatory strategy
• Debriefing: what works and what doesn't
Richard Peck, Vice President/Regulatory Affairs, Lupin Atlantis (CONFIRMED)</td><td>11:25 Support biosimilar acceptance by giving clinician and patient control using routine diagnostics serum concentrations measurements for biologics/biosimilars- real life data
• Experience from routine diagnostics on concentration and ADA measurements
• One dose/ multitude of serum levels; impact of immunogenicity on PK
• Validation of PK/ADA assays for originators for biosimilars; routine diagnostics vs. FDA/EMA registration
Annick de Vries, Director Bioanalysis, Sanquin (CONFIRMED)</td></tr>
<tr><td>11:50</td><td>Biosimilar regulations in Jordan
• How biosimilar regulations have evolved in Jordan
• Major articles in our guidelines
• Challenges faced with Biosimilars
Rana Musa al-ali "Malkawi", Head of Clinical Studies, Jordan FDA (CONFIRMED)</td><td rowspan="2">11: 45 Biosimilars: Clinical data requirements – have the regulators got it right?
• Why do biosimilars differ from generic drugs?
• Drawing on the totality
• What residual uncertainties need to be addressed by clinical data?
• Challenges and value of therapeutic equivalence trials
Cecil Nick, Vice President, Biotechnology, PAREXEL (CONFIRMED)</td></tr>
<tr><td></td><td>Regulatory experience to date on biosimilar safety</td></tr>
</table>

12:15	**Uwe Gudat,** Head of Clinical Safety & Pharmacovigilance, **Fresenius Kabi** (CONFIRMED)	**12:05 The value of real-world evidence in understanding the NOCEBO effect** • Perception of biosimilars: awareness and communication gaps • A common phenomenon known as the nocebo effect can impact outcomes • Strategies to minimize the possibility of a nocebo effect with biosimilar agents **Mourad Farouk Rezk,** Executive Director, Global Head Medical Affairs Biosimilars, **Biogen** (CONFIRMED)
12:40	**Sustaining and harmonising biosimilars through WHO international standards** • Concept of International Standardisation • Recent developments in WHO International Standards for Biosimilar Medicines including monoclonal antibodies • Future plans for WHO Standards for Biosimilars **Meenu Wadhwa,** Section Leader, Cytokines & Growth Factors Section, **NIBSC** (CONFIRMED)	**12:25 Panel discussion: impact of analytics innovation in biosimilar development and the role of clinical data** • To what extent do we need phase III clinical trials? • Strategies to address residual uncertainty • Where will be in 10 years' time? **Moderator: Cecil Nick**, Vice President, Biotechnology, **PAREXEL** (CONFIRMED) **Rana Musa al-ali "Malkawi",** Head of Clinical Studies, **Jordan FDA** (CONFIRMED) **Mourad Farouk Rezk,** Executive Director, Global Head Medical Affairs Biosimilars, **Biogen** (CONFIRMED) **Annick de Vries,** Director Bioanalysis, **Sanquin** (CONFIRMED)
13:05	**Networking lunch**	
	IP and Legal Considerations for Biosimilars **HELVETIA 1**	**Biosimilar Sustainability** **HELVETIA 2**
	Chair: Stacie Ropka, Partner, **Axinn** (CONFIRMED)	**Chair: Philip Schneider,** Chair, International Advisory Board, **Alliance for Safe Biologics Medicines** (CONFIRMED)
14:35	**Latest updates in US biosimilar litigation** **Tim Shea,** Director **Sterne Kessler Goldstein and Fox Plc** (CONFIRMED)	**What responsibility do payers have to foster a sustainable market for biosimilars? A Swedish perspective** • Lowest price tendering; Good or bad? • Brand confusion. A problem for health care professionals • Should payers accept a price range? **Gustaf Befrits,** Health Economist, **Stockholm County Council** (CONFIRMED)
14:55	**Biosimilars – some in-house perspectives** • How recent developments might influence strategy among biosimilar developers **Alastair Sayce,** Head Biologics IP, **Teva Pharmaceuticals** (CONFIRMED)	**The need for biosimilar sustainability for long-term benefits of the healthcare systems** • Contribution of Biosimilars to Sustainable Healthcare Systems • Country Scorecards for Biosimilar Sustainability – a market assessment • Policy recommendations to improve sustainability of the biosimilars market **Kelly Burke,** Senior Director Biologics, Europe, **Mylan and Medicines for Europe** (CONFIRMED)
15:15	**Panel discussion: What legal strategies can be adopted to address patent challenges with products with substantial patent portfolios**	**Hurdles in biosimilar development** • Navigating the Biosimilar Regulatory Landscape • Challenges on Biosimilar Market Adoption • Overcome Barriers of Biosimilars

	• What can be done to tackle big patent portfolios? **Moderator: Stacie Ropka,** Partner, **Axinn** **Alastair Sayce,** Head Biologics IP, **Teva Pharmaceuticals** (CONFIRMED) **William Adams,** Patent Attorney **Knobbe Matens** (CONFIRMED) **Tim Shea,** Director **Sterne Kessler Goldstein and Fox Plc** (CONFIRMED)	**Alvin Luk,** Senior Vice President & Chief Medical Officer, **Shanghai Henlius Biotech** (CONFIRMED)
15:35		**State of the art analytical methods for originator and biosimilar characterization** • Critical Quality Attributes ranking • Multi-dimentional analytical workflows • Multi-level mAbs and Fc-fusion proteins characterization **Alain Beck,** Senior Director, CMC and developability, **Pierre Fabre** and Associate Editor, **mAbs** (CONFIRMED)
15:55	**Afternoon refreshments**	
16:00-16:45	**ROOM: RIO** **WORKSHOP: Education of healthcare professionals and patients** **Kalveer Flora**, Rheumatology Specialist Pharmacist, Deputy Chair, Rheumatology Pharmacists UK, Pharmacy Department, Northwick Park, **Central Middlesex and Ealing Hospital** (CONFIRMED)	
	Biosimilar Sustainability and the Future of Biosimilars **HELVETIA 1&2**	
	Chair: Margaret (Maggie) Dolan, Associate Director Market Access Eu Biosimilars, **Biogen** (CONFIRMED)	
17:00	**Orphan drugs as biosimilars - is there a future?** • Orphan Biosimilar Clinical development -what needs to change? • Do regulations support orphan Biosimilar development? **Uwe Gudat,** Head of Clinical Safety & Pharmacovigilance, **Fresenius Kabi on behalf of** **Barbara Valenta-Singer**, Chief Medical Officer, **Fresenius Kabi**	
17:20	**Successes and future direction of biosimilars in Europe** • What biosimilars have done to sustain healthcare but what about sustainability of biosimilars? • Do we need a change in direction? • Vision moving forward **Steinar Madsen,** Medical Director**, Norwegian Medicines Agency** (CONFIRMED)	
17:40	**Closing keynote discussion: stakeholder collaboration** • How can patients, physicians, payers and biosimilar developers work together to ensure successful roll-out of biosimilars? • Patient and physician education • The challenges of implementing a biosimilar transition plan • Managing the concerns of various stakeholders **Moderator: Margaret (Maggie) Dolan,** Associate Director Market Access Eu Biosimilars, **Biogen** (CONFIRMED **Steinar Madsen,** Medical Director**, Norwegian Medicines Agency** (CONFIRMED) **Kalveer Flora**, Rheumatology Specialist Pharmacist, Deputy Chair, Rheumatology Pharmacists UK, Pharmacy Department, Northwick Park, **Central Middlesex and Ealing Hospital** (CONFIRMED) **Gustaf Befrits,** Health Economist, **Stockholm County Council** (CONFIRMED) **Andrew Spiegel,** Executive Director, **Global Colon Cancer Association** (CONFIRMED)	
18:20	Chair's closing remarks	
18:20	**End of Conference – Drinks Reception**	