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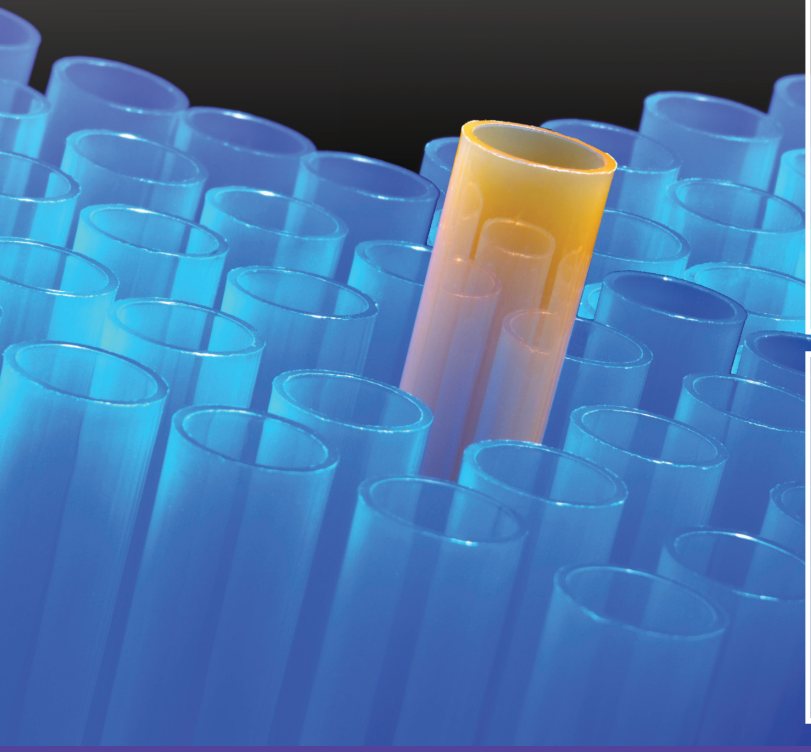

Chairman:

Richard DiCicco, Chairman,
Harvest Moon Pharmaceuticals USA, Inc.

Key Speakers Include:

- **Shahin Kauser,** Senior Scientific Assessor, **MHRA**
- **Chris Teale,** Vice President Europe, **GfK**
- **Bracha Timan,** Director, Israel Site Head, Global Bioassays and Technology, Global R&D, **Teva**
- **Takashi Kei Kishimoto,** Chief Scientific Officer, **Selecta Biosciences**
- **Karsten Roth,** Director Clinical Operations, **Cinfa Biotech GmbH**
- **Alan Sheppard,** Principal, Global Generics and Biosimilars, **IMS Health**
- **Steinar Madsen,** Medical Director, **Norwegian Medicines Agency**

Business Benefits for 2015:

- **HEAR** the latest on the evolving regulatory biosimilar landscape and review the guidelines
- **GAIN** understanding on the barriers being faced for market access and commercialisation of products through case-study led presentations
- **FOCUS** on the global market developments with case studies on emerging markets of biosimilars and assessing the trends we are currently seeing
- **ASSESS** and review in-depth protein characterisation and analytical comparability to efficiently and effectively collect data

TWO INTERACTIVE HALF-DAY WORKSHOPS

PRE-CONFERENCE WORKSHOP
Tuesday 29th September 2015, 1.00pm - 5.30pm

A: An Update on Legislative and Regulatory Developments in the United States and Europe affecting approval and market access of biosimilars

Workshop leaders: **Lincoln Tsang,** Partner and **Daniel Kracov,** Partner, **Arnold & Porter LLP**

POST-CONFERENCE WORKSHOP
Friday 2nd October 2015, 8.30am - 12.30pm

B: Biosimilars - Understanding the Regulatory Processes and the Commercial Realities

Workshop leader: **Peter Wittner,** Senior Consultant, **Interpharm Consultancy**

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6th Annual Biosimilars & Biobetters

Day One | Wednesday 30th September 2015

8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**
Richard DiCicco, Chairman, **Harvest Moon Pharmaceuticals USA, Inc.**

Regulatory Landscape

9.10 **Biosimilars' Long Term Potential to Wipe Out Innovation Budgets**
- What is long term: 2017-2020 or 2021-2030?
- Biosimilars global forecast 2017-2020 and third wave biosimilars 2021-2030
- How the market will change with multiple biosimilars of the same originator product
- Regulatory changes necessary to maximize biosimilars potential


Richard DiCicco, Chairman, **Harvest Moon Pharmaceuticals USA, Inc.**

The US Market

9.50 **Blockades to U.S. Biosimilar Entry and What to do About Them**
- The BPCIA 'Patent Dance' requires complex analyses of patent information to be exchanged between biosimilar and reference product manufacturers
- We provide tools to facilitate analysis of large patent portfolios and resolution of patent issues


Robin A Chadwick, Principal, Biotechnology, **Schwegman Lundberg Woessner**

10.10 **Non-BPCIA Resolution of IP litigation Issues Concerning Biosimilars in the U.S.**
- Low cost, less time consuming quasi litigation actions including ex parte and interpartes review in the U.S. PTO
- Declaratory Judgment Actions as an alternative to BPCIA pursuant to recent U.S. federal Case Law


Albin (Jim) Nelson, Senior Principal and Owner, Adversarial Proceedings/ Pharma & Biotech, **Schwegman Lundberg Woessner**

10.30 **Morning Coffee**

Patent Litigation

11.00 **Patent litigation of biologics - past, present and future**
- The story so far - biotech cases in the patents courts - Brief history of bio patent cases so far
- What's being litigated now? Whatever is then public
- Is biotech litigation so different from small molecule litigation? Review of differences and similarities
- Does biotech litigation need a different strategy? E.g. preliminary injunctions less likely in UK as no immediate price crash; will and should biotech patents opt in or out of the UPC?
- What's next?



Christopher Stothers, Partner, Intellectual Property Litigation, **Arnold & Porter (UK) LLP**
Kathy Osgerby, Associate, Intellectual Property, **Arnold & Porter (UK) LLP**

EU and Global Market Developments

PART ONE

11.40 **Biosimilars and the use of medical devices**
- Opportunites for differentiation where differentiation is limited by regulation
- Ensuring compliance within the EU and US – component perspective
- Usability engineering - should the same syringe be used?


Dirk Kreder, Founder & CEO, **Anteris Medical GmbH**

12.20 **Networking Lunch**

1.30 **Case Study: Emerging Markets for biosimilars**
- New biosimilars guidelines in China - key points and challenges
- Assessing a global marketing strategy for a successful biosimilar business
- What trends are we currently seeing in the biosimilars market?


Michel Mikhail, Expert in Biosimilars, **Germany**

2.10 **Case Study: Creating Biobetters with Improved Efficacy and Safety by Addressing Product Immunogenicity With Tolerogenic Nanoparticles**
- The forthcoming flood of biosimilars will create a highly competitive, low margin marketplace. There will be a competitive advantage for biobetters that are differentiated based on their efficacy and safety profile.
- Anti-drug antibodies compromise the utility of many biologic drugs by neutralizing drug efficacy, modulating pharmacokinetics, and/or causing adverse events.
- We have developed tolerogenic synthetic vaccine particles (SVP) that are capable of inducing durable immune tolerance to biologic drugs. We will present case examples using tolerogenic SVP with adalimumab and pegylated uricase.


Kei Kishimoto, Chief Scientific Officer, **Selecta Biosciences**

2.50 **Afternoon Tea**

Market Access and Commercialisation

3.20 **Market outlook - What's the future of biosimilars?**
- Understanding and reviewing current data regarding the hurdles in commercialisation of biosimilars
- Evaluating market entry - what's on the horizon?
- Assessing Cost reductions vs. demand
- Looking at market access initiatives on globalisation


Alan Sheppard, Principal, Global Generics and Biosimilars, **IMS Health**

ROUND TABLE DISCUSSION

4.00 **Reviewing the sustainability of the biosimilars market - "Where stakeholders align and policies collide"**
- Understanding the multi-stakeholder definition of sustainability
- Identifying the factors required for a sustainable European biosimilars medicines market
- Reviewing the perspectives of all stakeholders; Clinicians, Patients, Payers, Politicians/Policy Makers, and Industry (biooriginal, biosmilar, and biobetter)
- Looking to the future: Ideal World versus Real World


Chris Teale, Vice President Europe, **GfK NOP Ltd**

4.40 **Chairman's Closing Remarks and Close of Day One**

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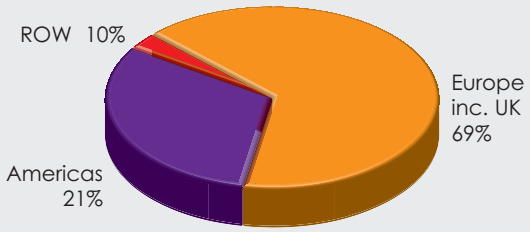

6th Annual Biosimilars & Biobetters

Day Two | Thursday 1st October 2015

8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**
Richard DiCicco, Chairman, **Harvest Moon Pharmaceuticals USA, Inc.**

Pharmacovigilance of Biosimilars

OPENING ADDRESS

9.10 **Safety First! "Totality of Evidence" and residual risk**
- Building the bridge between analytical characterization and clinical safety
- How much confidence on safety can the clinical program offer?
- Can we extrapolate safety across indications?
- Explaining "totality of evidence" to reassure clinicians
- Tailored post-launch pharmacovigilance: not too little, nor too much

Uwe Gudat, Head of Safety Biosimilars, **Merck Serono**

9.50 **KEYNOTE ADDRESS - UK regulator's experience of PV and RMP for biosimilars**
- What's new in the overarching biosimilar guideline regarding pharmacovigilance?
- How traceable are ADRs for biosimiliars reported to the UK Pharmacovigilance database?
- What types of post authorisation studies (e.g. registries) are requested?
- What other enhanced pharmacovigilance activities may be necessary?
- What types of additional risk minimisation measures may be necessary?

Shahin Kauser, Senior Scientific Assessor, **MHRA**

10.30 **Morning Coffee**

EU and Global Market Developments

PART TWO

11.00 **Leading the strategy to demonstrate Biosimilarity as support to Biosimilar projects**
- Biosimilarity assessment - from stepwise approach to fingerprint analysis
- Strategic considerations for successful support Biosimilar Development
- Totality of evidence - challenges and obstacles for setting an appropriate fingerprint model for biosimilarity assessment
- Monoclonal antibodies biosimilarity assessment - Case study will be presented

Bracha Timan, Director Head of Bioassays & Technology, **TEVA Pharmaceutical Ltd. Israel**

11.40 ***Session Reserved for Paul Greenland,**
Vice President- Biologics, **Hospira**

12.20 **Networking Lunch**

*Subject to Final Confirmation

1.30 **Switching patients to biosimilars: Interchangeability/ Substitution**
- Reviewing the switching study in Norway
- Addressing the standard of bioequivalence guidance for standard generics to gain further understanding
- Why generics accepted and biosimilars are not?

Steinar Madsen, Medical Director, **Norwegian Medicines Agency**

2.10 **Clinical Development Strategies for Biosimilars - A Mid-Size Pharma Perspective**

Karsten Roth, Director Clinical Operations, **Cinfa Biotech GmbH**

2.50 **Afternoon Tea**

Protein Characterisation and Analytical Comparability

3.20 **An automated high throughput platform for the assessment of potency of biosimilars**
- Assessing a more high throughput and cost effective approach
- What considerations should be made in the development of biosimilars?
- Exploring Glycosylation

Michael Tovey, INSERM Director of Research, Laboratory of Biotechnology and Applied Pharmacology, **Ecole Normale Supérieure de Cachan**

4.00 **How do you collect data efficiently and effectively?**
- Assessing how to clean data when building predictive Models
- Reviewing calibration maintenance and PATs
- Glycosylation - Helping scale-up innovation, what do you need to know?

Julian Morris, Technical Director, Centre for Process Analytical Control Technology, **Strathclyde University**

4.40 **Chairman's Closing Remarks and Close of Day Two**

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HALF-DAY PRE-CONFERENCE WORKSHOP A
Tuesday 29th September 2015
1.00pm - 5.30pm
Holiday Inn Kensington Forum, Central London, UK

An Update on Legislative and Regulatory Developments in the United States and Europe affecting approval and market access of biosimilars

Workshop leaders:
Lincoln Tsang, Partner and **Daniel Kracov**,
Partner, **Arnold & Porter LLP**

Overview of the workshop:

The workshop will provide practical insights into and updates on the current US and EU regulatory landscape. Areas to be addressed will include:

An overview of the legal/regulatory frameworks for biosimilar approvals in the EU and U.S. Experience to date and lessons learned under current approval pathways. Important issues and controversies, such as standards for approval, nomenclature, substitutability, extrapolation across indications, "biobetters" and exclusivities.
Status of pathways for resolution of patent disputes relating to biosimilars. Overview of payment issues relating to biosimilars.

Why should delegates attend this workshop:

The workshop is designed to be interactive and provide an opportunity for delegates to exchange views on the evolving regulatory landscape and factors that influence the approval and subsequently uptake of biosimilars. Delegates will obtain a grounding in the U.S. and EU approval frameworks for biosimilars, as well as an understanding of the key issues faced by companies in the field.

Programme:

1.00 **Registration & Coffee**

1.30 **Introduction and Opening Remarks**

2.00 **Session 1: An overview of the legal/regulatory frameworks for biosimilar approvals in the EU and U.S.**
- Reviewing experience to date and lessons learned under current approval pathways

2.30 **Session 2: Addressing the Challenges currently being faced**
- Important issues and controversies, such as standards for approval, nomenclature, substitutability, extrapolation across indications, "biobetters" and exclusivities

3.30 **Coffee break**

4.00 **Session 3: Status of pathways for resolution of patent disputes relating to biosimilars**
- Overview of payment issues relating to biosimilars

5.00 **Discussion and Q&A**

5.30 **End of Workshop**

About the workshop leaders:

Lincoln Tsang is a partner of Arnold & Porter LLP. His practice is focused on the life sciences industry including pharmaceuticals, biotechnology, medical devices, in vitro diagnostic devices, cosmetics, and food with particular emphasis on the intersection of the law and public policy. By ministerial appointment, he currently serves as a Commissioner of the British Pharmacopoeia Commission where he chairs the biologicals and biotechnology sub-committee and co-chairs the nomenclature committee. He was appointed by UK Health Ministers to serve for two terms as a board member of the National Institute for Biological Standards and Control.. He was head of biologics of the UK Regulatory Authority for 13 years. During his tenure, he served as an advisor to the European Medicines Agency on its various advisory committees; European Commission; European Directorate for the Quality of Medicines, the Council of Europe as well as the World Health Organization on matters relating to regulation and international trade of pharmaceutical, biological and medical technology products.

Daniel Kracov is a partner at Arnold & Porter LLP, where he co-chairs the firm's FDA and Healthcare Practice Group. Mr. Kracov assists clients, including investors, start-up companies, trade associations, and large manufacturing companies, in negotiating the legal requirements relating to the development, approval, and marketing of drugs, biologics, and medical devices. He routinely handles FDA inspections, investigations, and enforcement matters. He also helps clients develop global corporate compliance programs, conducts compliance reviews and audits, and manages regulatory due diligence for financings, mergers and acquisitions. He has a widely-recognized experience in biomedical product-related public policy matters, including Congressional investigations and FDA-related legislative initiatives. His expertise in FDA matters has been recognized by Chambers, the Legal Times, and numerous other publications.

HALF-DAY POST-CONFERENCE WORKSHOP B
Friday 2nd October 2015
8.30am - 12.30pm
Holiday Inn Kensington Forum, Central London, UK

Biosimilars - Understanding the Regulatory Processes and the Commercial Realities

Workshop leaders:
Peter Wittner, Senior Consultant,
Interpharm Consultancy

Overview of workshop:

This workshop aims to give participants a good overview of the whole topic of Biosimilars while investigating some topics in more depth. Biosimilars have attracted a great deal of interest and represent a new generic frontier as it is thought that lower levels of competition will lead to higher margins in an industry notorious for its generally low margins.

Lower regulatory barriers in less regulated markets have allowed a Biosimilars market to take off, but higher regulatory barriers in Europe and issues of interchangeability have resulted in slow progress for those already in the market. Across the Atlantic, the situation is changing with the long awaited legislation enabling the first Biosimilars registration. How will the market develop there as multinational players start to enter?

Why should delegates attend this workshop:

This workshop will provide you with:-

- A good overview of the Biosimilars picture across the world
- An overview of the barriers to entry
- Insight into the varying regulatory approaches prevailing in different regions
- An understanding of the commercial situation as it is now and how it is likely to develop in the future
- Enough background to determine whether entering the Biosimilars market is an appropriate strategy for their company

Programme

8.30 **Registration & Coffee**

9.00 **Introductions and Opening Remarks**

9.15 **Session 1: Overview - Biosimilars? Biogenerics? Follow-on Biologicals?**

- What are we actually talking about?
- Summary of issues affecting Biosimilars
  - Regulatory
  - Commercial
  - Legal/IP
- Interchangeability – what is the issue?

10.00 **Session 2: The regulatory process and its pitfalls**

- Europe - a straightforward case
  - EMEA guidelines
  - Overview of successful and failed applications
- US - the juggernaut begins to move
- India, China and other countries?

10.45 **Coffee break**

11.50 **Session 3: Biosimilars - the commercial reality**

- What is the big attraction?
  - Biologicals market and prospects
- The story so far...
  - Europe and the USA
  - Asian markets and Latin America
- Patents, IP and other issues
  - What are the patent issues?
  - Interchangeability - a potential roadblock
  - Differing national legislation
- Where do Biosimilars go from here?

12.15 **Discussion and Q&A**

12.30 **Close of Workshop**

About the workshop leader:

Peter Wittner, B.Sc., is an independent consultant specialising in the commercial aspects of generics with more than 35 years' pharmaceutical experience. In one of his industry roles, he joined the Indian generic leader Ranbaxy as Managing Director to help set up its UK business before returning to consultancy work **(www.interpharm-consultancy.co.uk).**

He previously headed the European Sales & Marketing department of the UK generics companies Evans Medical, which later became Medeva, and H.N. Norton, which later became part of IVAX and subsequently Teva.

Peter is a regular speaker at generic conferences, has run Biosimilars workshops for a number of organisations as well as conducting training seminars. He has written a number of reports on generics industry topics.

BIOSIMILARS & BIOBETTERS

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Workshops: Tuesday 29th September & Friday 2nd October 2015, Holiday Inn Kensington Forum, Central London, UK

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