Biopharmaceutical Production Series

Benchmark your biosimilar products against your competitors

Presenting Informa Life Sciences' 6th Annual

BIOSIMILARS

Gain access to the global biosimilars market, discover which products to watch and learn how to avoid costly pitfalls

Wednesday 18 - Thursday 19 November 2009, Mövenpick Hotel, Berlin, Germany

Highlights this year:

- ✔ **Explore** the latest developments in the US. What are the upcoming future opportunities and challenges?
- ✔ **Understand** the dynamics of the EU market and the progress of registered biosimilars
- ✔ **Learn** what the future could hold for biosimilar mAbs, their place in the EU market and how to address comparability studies
- ✔ **Equip** yourself with key information on regulatory, political and legal issues impacting the biosimilar field
- ✔ **Analyse** regulatory expectations on a global basis and discover further information on development costs and the potential future impact in emerging markets
- ✔ **Update** your knowledge on advancements in biosimilar comparability, immunogenicity, formulation and pharmacokinetics

Keynote speakers:

- **Dr Gillian Cannon,** *Executive Director Commercial Operations,* **Merck BioVentures,** USA
- **Dr Steffen Gross,** *Laboratory Head and Scientific Assessor (Quality, Non-clinical), Deputy Head Section Monoclonal and Polyclonal Antibodies,* **Paul-Ehrlich-Institut,** Germany
- **Dr Andreas Seidl,** *Head of Analytics and QC,* **Sandoz,** Germany
- **Richard DiCicco,** *Chairman,* **Harvest Moon Pharmaceuticals USA, Inc.,** USA
- **Dr Dhananjay Patankar,** *Chief Technical Officer,* **Intas Biopharmaceuticals Ltd,** India
- **Professor Georg-Burkhard Kresse,** *VP Biologics Research Strategy and Communication,* **Roche Pharma Research,** Germany
- **Dr Louis-Christian Clauss,** *General Co-ordinator Regulatory and Clinical,* **LFB,** France
- **Dr Volker Sandig,** *Vice President Cell and Vector Biology,* **ProBioGen AG,** Germany
- **Dr Fritz Sörgel,** *Director,* **Institute for Biomedical and Pharmaceutical Research,** Germany

Pre-Conference Workshop X: Tuesday 17 November 2009

Immunogenicity Considerations with regard to EPO Biosimilar Development

Explore the challenges of pharmacovigilance, risk assessment and how to ensure analysis of your safety issues receives a positive risk/benefit recommendation

Post-Conference Workshop Y: Friday 20 November 2009

How to Make and Navigate a Biosimilars Highway to Success

Assure your project achieves global success by overcoming crucial developmental and regulatory hurdles

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"Good event with a lot of cross-exchanging of views between innovator and biosimilar companies as well as doctors" *Intas Pharmaceuticals*

PRE-CONFERENCE WORKSHOP X
Tuesday 17 November 2009

Immunogenicity Considerations with regard to EPO Biosimilar Development

Registration 09.30 • Start 10.00 • End 16.00
Lunch, morning and afternoon refreshments provided

Introduction
The production process of any biopharmaceutical is complex. Duplication of this process to produce a biosimilar can be very difficult and the immunogenicity profile of the biosimilar compared to the reference product can be altered significantly. Immunogenicity, including lack of efficacy, is thus a safety problem that has to be taken into account.

This workshop will explore the challenges of pharmacovigilance and risk assessment using the biosimilar Erythropoietin (EPO) and the related rise in PRCA EPO-induced cases as an example. Emphasis will include the analysis of safety issues in order to receive a positive risk/benefit recommendation.

Key topics covered include:
• Quality • Efficacy • Safety • Risk benefit • Analysis of safety issues

Why should you attend?
Biosimilars have the potential to induce an unwanted immune response in treated patients. This can be influenced by various factors, including patient and/or disease-related factors and product-related factors. It is vital that the factors contributing to or triggering this response are realised and understood. Attending this workshop will equip you with vital knowledge required to overcome the challenges in the risk assessment of biosimilars.

Led by:
Dr James Harris, *CEO,* **Healthcare Economics LLC,** USA

DAY 1: Wednesday 18 November 2009

8.15 Registration

8.50 Chairperson's opening remarks

Understanding the Current Market and Future Regulatory Pathway for Biosimilar Approval in the US

9.00 **Market Overview from a Dual Perspective** (Keynote)
Biologics have transformed the way we treat disease and novel therapies promise to play a pivotal role in the future of medicine. In addition, pending patent expiries are generating enhanced interest in the development of biosimilars that hold the potential to enhance patient access. This presentation will provide an overview of this rapidly evolving market from these two perspectives.
Dr Gillian Cannon, *Executive Director Commercial Operations,* **Merck Bioventures,** USA

9.35 **Defining the Current US Regulation and Exploring the Development of Biosimilars in the US**
Overview of the current bills and proposed legislation in the US and what this could mean for the future. The FTC report released on June 10th 2009 will be discussed with its recommendations for data exclusivity. The US status will be reviewed with respect to what has already happened in the EU.
Dr Liz Fuller, *Director Life Sciences Regulatory (US Qualified),* **Wragge & Co.,** UK

10.10 **Opportunities and Challenges for Biosimilars within the USA**
Assessing the promise and potential for biosimilars has been and continues to be an area of great interest. Europe has embraced these new products and now the USA has started to put the pieces in place to spur their development and market entry. This presentation will focus on such topics as the recent progress in biosimilars development, regulatory update on bioequivalence, interchangeability and substitution for biosimilars, provider perspectives and acceptance of biosimilars, payer perspectives, formulary acceptance, and examining the viability of biosimilars.
Dr James Harris, *CEO,* **Healthcare Economics LLC,** USA

10.45 Coffee break

Current Legislative and Regulatory Status of Biosimilars in Europe and Globally

11.15 **Status of Registered Biosimilars Products on the EU Market**
Overview of current biosimilar products on the EU market will be focused on. The authorisation procedure used and the main problems that have arisen in the commercialization with the interchangeability and substitution with originator, International Nonproprietary Names and pharmacovigilance will also be reviewed.
Professor Paola Minghetti, *Faculty of Pharmacy,* **University of Milan,** Italy

11.50 **Regulatory Expectations on a Global Basis**
Industry, patient and payer expect biosimilars to be available globally. The main issue beyond patent protection is the lack of a harmonised approach to biosimilars or follow on proteins (FOP). One way to achieve this is through global standards such as the WHO guidance reference or the adoption of the European policy in other countries such as Australia, Canada or New Zealand. Another alternative is through national approval like in South America, Argentina, Brazil and Mexico or as in India and China.
Dr Louis-Christian Clauss, *General Co-ordinator Regulatory and Clinical,* **LFB,** France

12. 25 **Panel Discussion - Have biosimilars met industry expectations and what is the future outlook for 2012?**
This is your opportunity to discuss all your pressing concerns with our expert panel of speakers. To make the most of this session please e-mail any questions in advance to the conference producer **amelia.way@informa.com**

12.45 **Spotlight Session**
Technology and product providers will provide interactive educational tutorials which address the benefit of their technology or product in the field of Biosimilars in Asia-Pacific. If you would like to host a tutorial please contact **christopher.handsley@informa.com Tel: + 44 (0)20 7017 7278**

13.15 Lunch

14.30 **Biosimilars from India: Challenges and Opportunities in Moving to Europe**
Biosimilars have been manufactured and sold in the Indian market for at least a decade. As Indian manufacturers look to global markets, particularly Europe, they are presented with a combination of factors: different regulatory systems and expectations, different cost and pricing mindsets, different manufacturing challenges. However, there are also unique advantages that, properly exploited, can make Indian biosimilars important players in the global market in coming years.
Dr Dhananjay Patankar, *Chief Technical Officer,* **Intas Biopharmaceuticals Ltd,** India

15.05 **Biosimilar Regulatory and Development Costs in Emerging Markets and how they will Impact the Global Biosimilars Market in the Future**
The development costs of biosimilars and copy biopharmaceuticals are influenced by the regulatory guidelines and laws in the pharmemerging markets such as South Korea, Brazil, Turkey, China, India, Russia and Mexico. The seven leading pharmemerging markets and thirteen others will be presented as the current sites where biosimilar and copy biopharmaceutical profits can be optimized, near term. The supply side of copy biopharmaceutical products from these pharmemerging markets will be presented, because the products can enter certain regulated markets in the near term. Many examples will be presented showing the development costs and profits.
Richard DiCicco, *Chairman,* **Harvest Moon Pharmaceuticals Inc.,** USA
Margaret Hsiao, *Chief Executive Officer,* **Harvest Moon Pharmaceuticals Inc.,** USA

15.40 Coffee break

Payer Perception and Pricing and Reimbursement of Biosimilars

16.15 **Physician and Payer Perceptions of Biosimilars: Barriers and Opportunities**
While biosimilars may seem financially compelling to some parties, cost savings will not be fully realized without physician acceptance. Year-over-year, Decision Resources' primary research has shown a trend toward both awareness of and reluctance to prescribe biosimilars among physicians. This presentation will examine evolving physician and payer perceptions and how these changes affect forecast sales of brands and biosimilars.
Michael Malecki, *Product Manager, New Products,* **Decision Resources, Inc.,** USA

16. 50 **Pricing and Reimbursement of Biosimilars**
Pricing and market access dynamics of biosimilars are influenced by various stakeholders and multiple drivers. Key stakeholders are manufacturers of original brand and biosimilars as well as their customers (payers, physicians and patients). Important questions to be addressed are: What is the pricing and access environment for biosimilars? What do payers want? How do customers perceive original and biosimilar? What are key future developments?
Thomas Buchholz, *Partner,* **Simon-Kucher & Partners,** Germany

17.25 Question and answer

17.40 Chairperson's closing remarks

DAY 2: Thursday 19 November 2009

8.30 Registration

8.50 Chairperson's opening remarks

Exploring the Development and Potential of Biosimilar Monoclonal Antibodies

9.00 **Biosimilar Monoclonal Antibodies – Where we currently stand**
Biosimilar mAbs may be a highly interesting commercial opportunity. However, mAbs are highly complex proteins due to size and multifunctionality, and their pharmacological mode of action involving both the Fab and Fc parts of the molecule. The presentation will discuss whether the EU regulatory framework is appropriate for biosimilar mAbs, technical hurdles, and the challenge to demonstrate non-clinical and clinical similarity of biosimilar mAbs to their reference products.

Professor Georg-Burkhard Kresse, *VP Biologics Research Strategy and Communication,* **Roche Pharma Research,** Germany

9.35 **Comparability of Biosimilar Monoclonal Antibodies**
Biosimilars such as plasma products or monoclonal antibodies are complex molecules and the comparability approach is a challenge for the manufacturers of these products. Currently the first monoclonal antibodies are entering the field and the comparability approach is a manner for debate. Comparability based on biophysical and biochemical characterization only is not sufficient and should be accompanied by appropriate preclinical and clinical studies. Recent experiences and discussion of general questions will be discussed.

Dr Steffen Gross, *Laboratory Head and Scientific Assessor (Quality, Non-clinical), Deputy Head Section Monoclonal and Polyclonal Antibodies,* **Paul-Ehrlich-Institut,** Germany

10.10 Coffee break

Comparability and Immunogenicity

10.40 **A Look at Comparability of Biosimilars**

Dr Andreas Seidl, *Head of Analytics and QC,* **Sandoz,** Germany

11.15 **Addressing Product Quality during Development of Biosimilar Products**
Higher yield and highest similarity in posttranslational modifications- a contradiction? The significance of differences in glycosylation will be considered along with emerging data on the comparability between alternative systems. Key questions to be answered include: What are the issues for different expression systems? To become a biosimilar do you need the same production system as the originator? The Regulatory view and case studies will also be considered and discussed.

Dr Volker Sandig, *Vice President Molecular Biology and Virology,* **ProBioGen AG,** Germany

11.50 **Analytical Methods for Comparability and Glycoprotein Characterisation**
This presentation will provide an overview of available physicochemical analytical methods, including mass spectrometry and other sophisticated instrumentation, for the characterisation of biosimilars and comparability analysis with a reference product. Strategies for primary and higher order structure determination will be discussed for products ranging from small proteins to glycoproteins, including antibodies, with reference to appropriate regulatory guidelines. Emphasis will be placed on techniques for PTM detection.

Dr Fiona Greer, *Director, Biochemical Services,* **M-Scan,** UK

12.20 **Spotlight Session**
Technology and product providers will provide interactive educational tutorials which address the benefit of their technology or product in the field of Biosimilars in Asia-Pacific. If you would like to host a tutorial please contact
christopher.handsley@informa.com Tel: + 44 (0)20 7017 7278

12.50 Lunch

14.00 **Biosimilar Immunogenicity**
In the field of nephrology since the late eighties the availability of recombinant human erythropoietin (rHuEPO) has markedly improved the management of anaemia. Today, erythropoiesis stimulating agents (ESA) are the main tool for anaemia correction in CKD patients, virtually eliminating the need for blood transfusions. Currently, the patents for some ESA have expired or are approaching expiration and a number of biosimilars manufacturers are aiming to share the market with "branded" ESA. This will probably lead overall to reduced treatment costs. However, a number of issues about bioequivalence and safety are still to be completely addressed. In particular these molecules need careful pharmacovigilance of possible occurrence of pure red cell aplasia. This is a serious adverse event related to ESA therapy. In this disease, epoetin-induced antibodies neutralize all the exogenous rHuEPO and cross-react with endogenous EPO.

Dr Lucia Del Vecchio, *Medical Assistant Department of Nephrology and Dialysis,* **A Manzoni Hospital,** Italy

Formulation and Pharmacokinetics

14.35 **How Important is Pharmacokinetics?**
This presentation will discuss the technical challenges, how to design a pharmacokinetic test and also the status of current analytical techniques used for determining bioequivalence.

Dr Fritz Sörgel, *Director,* **Institute for Biomedical and Pharmaceutical Research,** Germany

15.10 Coffee break

15.40 **Differentiating Biosimilars through Formulation**
Biosimilars are required to demonstrate pharmacokinetic profiles comparable to the corresponding innovator drugs. However, if the innovator drug formulations are protected by patents, biosimilars have difficulty entering the market unless they can be differentiated through new formulations. Arecor Limited has developed a protein stabilization technology which permits the development of new differentiated formulations for biosimilars with distinct advantages in that they possess superior stability profiles without infringing existing patents.

Dr Jan Jezek, *Principle Scientist,* **Arecor,** UK

Legal Issues and Strategies Surrounding Biosimilars

16.15 **Application of Patent Litigation Strategies to Biosimilars: Is there a Difference?**
Originator companies have designed and implemented patent litigation strategies aimed at ensuring continued revenue streams for their small molecule medicines. This presentation will provide an overview of these strategies and will examine whether they also apply to biosimilars. The presentation will also deal with launch strategies and possible defences for manufacturers' biosimilars.

Kristof Roox, *Attorney,* **Crowell & Moring,** Belgium

16.50 Question and answer

17.00 Chairperson's closing remarks

POST-CONFERENCE WORKSHOP Y
Friday 20 November 2009

How to Construct and Navigate a Biosimilar Highway to Global Success by Overcoming Regulatory and Development Hurdles

Registration 09.30 • Start 10.00 • End 16.00
Lunch, morning and afternoon refreshments provided

Introduction
This workshop will disclose information on how to assure your project achieves global success in the field of Biosimilars.

The current global situation does not allow for global development to be managed in a straight forward manner in the EU and USA. The requirements before starting a project in this field are very similar to the ones required for any business success strategy.

Key topics covered include:
- Creating a business / marketing strategy
- Project management of customer/patients/payers and authorities expectations
- Financial goals, budgeting and the net present value
- Handling the project with tight management and control in the company's main-stream strategy
- Securing solid financial resources
- Clinical, CMS and regulatory strategy are essential for creating a globally successful product

All these questions will be discussed in detail with successful examples of biosimilars that have accessed the global market.

Who should attend?
Regulatory affairs professionals, project leaders and business development managers wanting practical advice on overcoming the barriers to market

Led by:
Louis-Christian Clauss, *General Co-ordinator Regulatory and Clinical,* **LFB,** France

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