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Biosimilar DRUG DEVELOPMENT WORLD

Europe 2012

28 February – 2 March 2012, Millennium Gloucester Hotel, London, UK

Hear from

Mark McCamish
Head Global Biopharmaceutical Development
Sandoz International GmbH

Cyrus Karkaria
President, Biotech Division
Lupin Limited

Brian Hosung Min
Vice President, Strategic Business Development
Samsung

The Honorable Henry A. Waxman
Member of Congress
United States of America

Biosimilar regulatory update from:

Alexandre Moreau
Clinical Assessor in Oncology
Afssaps

Dr Marie-Christine Bielsky
Senior Medical Assessor, Biologicals and Biotechnology Unit, Licensing Division
MHRA

Dr Phul Parvinder
Pre-clinical Assessor
MHRA

More highlights Page 3 >>
Full programme Pages 4 - 6 >>

Navigate

Innovations in development for the biosimilar industry

Science led content
Get a detailed understanding of the complex science underlying the successful development and manufacture of biosimilar drugs See pages 4 and 5 >>

Key stakeholder input
Learn from the R&D and scientific experts helping to shape biosimilar development in the global environment See page 3 >>

Interactive & informative programme
Build the conference agenda to meet your business needs with an interactive agenda, networking opportunities, co-located event, panel discussions, Q&A and workshops See page 6 >>

Pre & post conference workshops:

Tuesday 28 February 2012
Successful registration of biosimilars and biobetters in the EU

Friday 2 March 2012
The evolving quality (chemistry and manufacturing) paradigm for biosimilars

All the details page 6 >>

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See page 8

"Excellent – the discussion was very good"

Director Market Intelligence, **US Pharmacopeia**

"Good discussion and information"

Associate Director, **Dr Reddy's Biologics Development Center**

"Excellent – top presentations by top speakers"

Vice President, **Jubilant Draximage**

The strategy and science behind successfully taking biosimilars from bench to market

The inaugural *Biosimilar Drug Development World Europe 2012* is set to provide the industry with the critical scientific and strategic knowledge and connections to help navigate the challenges in the development, production and launch of biosimilar medicines. The meeting unites a world class speaker panel of biosimilar and biotechnology scientific experts who are driving innovation in the biosimilar sector.

Register now to understand the underlying scientific techniques and tools needed to reduce risks and achieve excellence in the laboratory, clinic, manufacturing process and in facing regulatory hurdles.

Attend the first ever *Biosimilar Drug Development World* and learn innovative techniques and best practice in:

- Scientific foundations behind the development of biosimilars from the bench to market
- Biosimilar product development,
- CMC and comparative analysis
- Best practice processes for taking a biosimilar from cell bank to market
- Considerations for biosimilar manufacture, process development, scale-up and validation
- Non clinical studies for biosimilars
- Best practice in clinical trials design and execution
- The use of immunogenicity tools and techniques in development and the clinic

- Proven strategies in biosimilar pharmacovigilance and risk management
- Global regulatory requirements for biosimilars and the resulting impact on drug development, manufacture and clinical trials
- Quality
- Biobetter development strategies
- Monoclonal antibody regulatory backdrop and development considerations

World Generic Medicines Congress Europe 2012

Biosimilar Drug Development World Europe 2012 is part of the hugely successful global generic medicines series. The meeting is co located with the 6th Annual *World Generic Medicines Congress Europe 2012*, the world leading strategy event for CEO/VP/ Senior Directors addressing the development of generic medicines globally.

Industry sectors: biosimilar and generic manufacturers, pharma, biotech, CMOs and CROs

8 REASONS

Why you should attend Biosimilar Drug Development World 2012:

1. **Quality scientific content** Focused on the details of biosimilar development and manufacture
2. **Global speaker platform** This is a global industry so we have an international speaker panel to match, with key biosimilar developers from Asia, Europe and USA
3. **Biosimilars from lab to clinic and beyond** Addressing the full lifecycle of biosimilar development
4. **Additional in depth workshops** Delve deeper into 2 important topics including regulatory setting in Europe and CMC strategy
5. **Great networking opportunities** Make contact, plan who to meet and arrange meetings prior to the conference, take part in multiple networking sessions, continue and build those relationships following the event
6. **All key stakeholders in 1 room** including industry, regulators and academia
7. **Proven track record!** Quality is guaranteed as this is part of the hugely successful World Generic Medicines Congress series
8. **Packed agenda** Choose to attend for 2,3 or 4 days with 20 informative sessions, panel discussions, workshops and plenty of networking to keep you busy

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- meet and make contacts
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use your brain

A-list of industry experts

QbD concepts in biosimilar development

Susanne Richter, Lab Head DSP Development Cell Culture, **Sandoz Biopharmaceuticals**

Clinical trial requirements – is the extent and depth of trial requirements necessary?

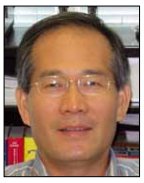
Deven Parmar, Vice President - Global Clinical Research, **Wockhardt**

Technical CMC strategies to increase profitability and minimize regulatory risk during biosimilar development

Dr Crawford Brown, Chief Executive Officer, **Eden Biodesign Ltd (Part of The Watson Group)**

Immunogenicity of biosimilars

Meenu Wadhwa, National Institute for Biological Standards and Control (NIBSC), Expert of the BMWP, **EMA**



Global biosimilar programme

Stanley Hong, Senior Vice President, Research and Development, **Celltrion**

Process considerations for taking a biosimilar from cell bank to market

Piotr Lassota, Scientific Director, **Polpharma Biologics**

Challenges in clinical trial design for biosimilars

Janet van Adelsberg, Senior Director, **Merck BioVentures**

Biosimilars - the devil is in the detail

Heinz Haenel, Diabetes Division R+D Projects, **Sanofi Aventis**

Process and quality consideration in developing the biosimilar Products

Partha Hazra, Senior Scientific Manager, R&D Biologics, **Biocon Limited**

Your event contact is
Sabrina Khamissa
+44 (0) 207 608 7055
skhamissa@healthnetworkcommunications.com

> "Very good subject matter with good speakers"
> Director Strategies, **Greenstone**

> "Great delegate mix and really good presentations, lots of relevant info"
> Deputy CEO, **Cipla Medpro**

20+ Biosimilar thought leading speakers

Day One Wednesday 29 February 2012

08.00 **Registration and morning refreshments**

08.50 **Opening remarks from the chair**

BIOSIMILAR MARKET HEALTHCHECK

09.00 **Worldwide experience in successful biosimilar development**

KEY NOTE

- Limited access to biologic therapies is an unmet medical need
- Technical challenges of achieving biosimilarity
- Justification for abbreviated clinical development programs
- Realities of commercialisation - are we successful in meeting patient needs?

Dr Mark McCamish, Head Global Biopharmaceutical Development, **Sandoz International GmbH**

09.30 **Global challenges in biosimilar development**

KEY NOTE

- With the current regulatory approach to biosimilars, no significant product price difference would be passed on to the ultimate payer or patient
- There is a clear need for more interaction between the regulator and biosmilars industry to harmonise understanding, ensure safety and not over burden the biosimilar company
- Challenges from CMC, clinical, commercialisation, safety and cost effectiveness perspectives
- Challenges in cost containment to make biosimilars more commercially viable and improve access

Dr Cyrus Karkaria, President, Biotech Division, **Lupin Ltd**

10.00 SPEED NETWORKING followed by morning refreshments

GLOBAL BIOSIMILAR REGULATORY AND APPROVAL PROCESSES

11.00 **European regulatory setting for biosimilars**

KEY NOTE

- Current regulatory requirements for biosimilar approval in Europe
- Regulatory documentation submission for biosimilars
- Regulatory and industry interaction – building a better regulatory setting for the biosimilar industry of tomorrow
- Review and update on mAb regulations in Europe

Alexandre Moreau, Clinical Assessor in Oncology, **Afssaps**
Dr Marie-Christine Bielsky, Senior Medical Assessor, Biologicals and Biotechnology Unit, Licensing Division, **MHRA**

12.00 **Pre clinical regulations for mAbs biosimilars**

- Update and analysis on the pre clinical regulatory requirements of monoclonal antibody biosimilar drugs

Dr Phul Parvinder, Pre-Clinical Assessor, **MHRA**

12.30 **Biosimilars in the US: clinical and analytical challenges**

- Overview of the US biosimilar's legislation and recent FDA activities
- Clinical and analytical challenges to demonstrating the highly similar nature of biosimilar products to their reference products
- Approaches to demonstrating interchangeability

William Egan, Vice President, **PharmaNet Consulting**

13.00 **Lunch**

14.00 **Congressional update and Q&A session on US legislation**

KEY NOTE

- Competitions vs access for affordable medicines
- Update of legislative pathway for biosimilars in USA

The Honorable Henry A. Waxman, Member of Congress, **United States of America**

PRODUCT DEVELOPMENT

14.30 **Technical CMC strategies to increase profitability and minimize regulatory risk during biosimilar development**

- Biosimilar developers face unique challenges as they seek to reduce Cost of Goods Sold whilst simultaneously maintaining essential similarity to innovator products
- How advances in biomanufacturing technologies and the design of innovative production strategies can speed development, increase market competitiveness, generate profitability and minimize risk

Dr Crawford Brown, Chief Executive Officer, **Eden Biodesign Ltd (part of The Watson Group)**

15.00 **Reference product selection and cell line development**

- Originator selection
- Validating stability
- Stable cell-line process development

Joe Zhou, CEO, **Genor Pharma (part of the Wison Group)**

15.30 **Afternoon refreshments**

PROCESS DEVELOPMENT AND MANUFACTURING

16.00 **Process considerations for taking a biosimilar from cell bank to market**

- Reverse engineering, upstream cell culture and downstream purification
- Scale up of manufacturing needs
- Improvement of yield
- Fermentation
- GMP
- Reproducibility

Piotr Lassota, Scientific Director, **Polpharma Biologics**

16.30 **QbD concepts in biosimilar development**

- The process determines the product
- Risk based approaches in biosimilar development
- Case studies from process development
- Chances and challenges in downstream processing

Susanne Richter, Lab Head DSP, Development Cell Culture, **Sandoz Biopharmaceuticals**

17.00 **Process and quality consideration in developing biosimilar products**

- Importance of proper analytical techniques
- Reference product selection and analysis
- Manufacturing considerations and challenges for biosimilars
- Specification

Partha Hazra, Principal Scientific Manager, Research and Development Biologics, **Biocon**

17.30 **Networking drinks reception**

19.30 GALA DINNER

Register for the gala dinner to relax and network over a few drinks and great food with your fellow attendees. Hear a truly inspirational speech from Pete Goss MBE who will share his thrilling adventure as the first Brit to complete the Vendée Globe, a nonstop single handed round the world yacht race.

Day Two Thursday 1 March 2012

8.50 **Opening remarks from the chair**
Dr. Fred Pritchard, PhD, Vice President, Global Drug Development, **Celerion**

CLINICAL TRIALS

9.00 **Clinical trial requirements – is the extent and depth of trial requirements necessary?**
- What could the clinical environment of tomorrow look like?
- Do patient's benefit from the current clinical environment or is existing data being repeated?
- Trial size requirements
- Statistical considerations for clinical trials
- Abbreviated trials

Deven Parmar, Vice President, Global Clinical Research, **Wockhardt**

09.30 **Early Stage Studies of Biosimilars**
- Comparability in the pre-clinical stage
- *In vitro* & *in vivo* analysis
- Considerations for the bioanalytical assays
- PK/PD studies
- Immunogenicity considerations

Dr. Raymond Farmen, PhD, Vice President, Global Bioanalytical Services, **Celerion**

10.00 **Challenges in clinical trial design for biosimilars**
- Key challenges in the reliable clinical trial design for the analysis of similarity between a biosimilar and originator in the global industry

Janet van Adelsberg, Senior Director, **Merck BioVentures**

10.30 **Morning refreshments**

11.00 **Global biosimilar clinical trials programme**
- Experience of developing biosimilars and conducting "global clinical trials" for our candidates
- Global trends for biosimilar development
- Desirable strategy and global clinical trials for biosimilar candidates

Stanley Hong, Senior Vice President, Research & Development, **Celltrion, Inc**

11.30 **Acceptable quality attributes of biosimilar molecule**
- General biosimilarity concept
- Case study - a Samsung molecule as an example
- Clinical data from a FIH study

Brian Hosung Min, Vice President, **Samsung**

BIOSIMILAR PHARMACOVIGILANCE

12.00 **Pharmacovigilance for biosimilars – preclinical and clinical safety considerations in development of biosimilars**
- Utilising non clinical and clinical data to plan pharmacovigilance for biosimilars
- Biosimilar Risk Management Plans
- Exploring known risks from the originator to develops risk management strategy
- Safety specification and pharmacovigilance plan documentation requirements
- Operational challenges in undertaking late phase studies (including observational studies, registries and surveillance)

Rakesh Dixit, Vice President, Research & Development Global Head, **MedImmune**

12.30 **Lunch**

BIOSIMILAR IMMUNOGENICITY

13.30 **Immunogenicity of biosimilars**
- Overview of Immunogenicity
- Immunogenicity testing – strength/weaknesses of different analytical techniques
- Assay design and validation for immunogenicity assessment
- Update on immunogenicity assessment of biosimilars

Meenu Wadhwa, Head, Cytokines and Growth Factors Section, **Biotherapeutics Group at the National Institute for Biological Standards and Control (NIBSC)**

BIOSIMILAR BEST PRACTICE

14.00 **Biobetters**
- Strengths and weaknesses of launching a product as a biobetter not biosimilar
- Scientific considerations in the development and manufacture of biobetters
- Differentiation challenges and strategies to making your product stand out from the originator

Dr Rustom Mody, Executive Vice President, **Intas Biopharmaceuticals Ltd.**

14.30 **Cold chain management for biosimilars**
- Stability studies of biotherapeutic proteins
- Evaluating temperature excursions and biopharmaceutical product stability (cold chain management)

Rajiv Dua, Research Executive, Quality Control, **Lupin Biotech**

15.00 **Afternoon refreshments**

15.30 **Biosimilars – the devil is in the detail**
- Biosimilars of insulins are never identical to the originator product by: possible immunogenicity, by products, synthesis, manufacturing process, organism to produce it and tertiary structure

Prof. Dr. Heinz Haenel, Diabetes Division Research and Development Projects, **Sanofi Aventis**

16.00 PANEL SESSION **Biosimilar drug type specialisation**
- mAb biosimilars seem to be on everyone's agenda what about other drug types?
- Is specialising in a specific product type a solid strategy?
- Skills and expertise needed to specialise

16.30 **Biosimilars regulations: Indian perspective**
- List of biosimilar products approved in India
- Case study of product development, manufacture and approval in India
- Major Indian players/manufacturers in the field of biosmilars
- Bioimilar regulations for therapeutic monoclonal antibodies in India

Smita Singhania, Vice President Regulatory Affairs, **Cipla Biomab Ltd**

17.00 **Closing remarks from the Chair**

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PANEL SESSION

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Pre and post-conference workshops

Tuesday 28 February 2012

Successful registration of biosimilars and biobetters in the EU

Overview: Regulations for biosimilars are currently evolving in Europe, the US, and in many emerging countries. Europe has been in the forefront of Biosimilar regulation since 2001 when the EU created a pathway for the approval of Biosimilars. The EMA has since issued three overarching biosimilar guidelines, describing (I) general requirements, (II) quality, and (III) non-clinical and clinical development, and, in addition, a number of product class specific guidelines.

The hurdles are high for a successful registration of Biosimilars in Europe. So far, seven development programs for three product classes (somatropin, epoetin, filgrastim) have been completed successfully, whereas four programs have failed (interferon alfa, insulin, interferon beta, epoetin). Monoclonal antibodies are structurally even more complex, and once these medicines go off patent, they will inspire a next wave of follow-on developments. Our ability for thorough characterization has advanced tremendously, and the value of non-clinical data in the development of mAbs has been recognized. The use of quality-by-design principles, high-producer cell lines, and single use-manufacturing technologies may significantly reduce development timelines and costs.

The workshop will run from 9.00 AM - 3.30 PM and will include refreshments and lunch.

Workshop content:

- Implementing the EU Biosimilars guidelines
- Experiences with the EU biosimilar regulations and authorities
- What are the hurdles in developing EU and global quality Biosimilars?
- How to design successful development plans for EU Biosimilars and Biobetters?
- What are the upcoming EU Biosimilars guidelines including the EU biosimilar monoclonal antibody guideline telling us?
- How to develop a scientific advice strategy and a submission plan for successful EU Biosimilars and Biobetters approvals?

About your workshop leader:

Dr. Carsten Brockmeyer is the owner and Managing Director of Brockmeyer Biopharma GmbH, a consulting firm providing strategic and operational support for novel and biosimilar biopharmaceutical development. Dr. Brockmeyer is a pioneer in the development of biopharmaceutical and biosimilar medicinal products. He is a cell biologist and immunologist by training, with a strong background in analytics, immunology, biotechnology and pharmaceutical sciences.

Friday 2 March 2012

The evolving quality (chemistry and manufacturing) paradigm for biosimilars

Overview: This workshop will explore the manufacturing of biosimilars focusing on the similarities and differences for the biosimilar versus the reference drug. Emphasis will be placed on the unique manufacturing challenges of biosimilars, especially monoclonal antibodies. The workshop will provide an overview of the manufacturing of a biosimilar drug in addition to detailed insight into the key topics stemming from CMC challenges and opportunities.

The workshop will run from 9 – 3.30pm and will include refreshments and lunch. The day will include a number of additional biosimilar experts. Check out the website www.healthnetworkcommunications.com/biosimilar for up to date speaker listings.

Workshop content:

- Overview of CMC
- How does one minimize the risk of immunogenicity of the biosimilar, i.e., what bioanalytical studies can help to mitigate this risk?
- How does the biosimilar manufacturer develop processes that do not infringe on intellectual property?
- What are the challenges facing manufacturers of clinical grade biosimilar material, i.e. supplying adequate quantities of drug worldwide at competitive prices?
- How can the quality profile change throughout the product lifecyle? Is there such as things as "product drift"?
- What comparability assays need to be developed to support similarity of target binding and (potency) function of the biosimilar and reference drug? What are the state of the art bioanalytical methods being used in these bioassays for biosimilars?
- Panel discussion

About your workshop leader:

Anita M. O'Connor, MS, PhD, has over 20 years of experience in regulatory affairs and drug development for the pharmaceutical, medical device, food, and animal drug industry. She worked for FDA for 16 years including the CBER, CDER, CVM, CFSAN and OC. ANITA OCONNOR CONSULTING, advises clients on the regulatory and drug development process for innovator biopharmaceuticals and biosimilars. Anita O'Connor's educational background includes a BA in Biology and MS and PhD in Animal Science and Biochemistry from Amherst College, the University of Maryland and the University of Florida.

Becoming a sponsor or exhibitor

Biosimilar Drug Development World Europe 2012 is where the generic, biotech and innovator pharma industry, regulators and solution providers debate laboratory and clinical strategies, techniques and best practice.

It is a place where innovation is showcased, learning is done and new business contacts are made.

By bringing together senior level biosimilar development and manufacturing decision makers, *Biosimilars Drug Development World Europe 2012* provides an unrivalled platform to expose and find solutions to the most pressing scientific and strategic challenges. It is the perfect opportunity to identify and approach new business prospects.

PROMOTE YOUR COMPANY'S EXPERTISE & SERVICES. At no other conference will you be able to meet with such a high number and calibre of industry decision makers who are coming together specifically for advice & support in this environment.

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If you provide services & support in this area and you want to increase brand awareness and market share, then *Biosimilar Drug Development World* is an event you can't afford to miss.

Questions to determine your involvement

- Do you offer services and solutions that support the challenges faced in the Biosimilars industry?
- Could you benefit from introductions to and time spent with decision makers?
- Is it cost & time effective to meet multiple prospects & clients in one setting?

If your answer is yes to any of these questions, you should be participating at this event!

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Biosimilar DRUG DEVELOPMENT WORLD Europe 2012

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2 main days plus post workshop 29 Feb – 2 Mar	£1935 + VAT £387 = £2322	£2150 + VAT £430 = £2580	£2260 + VAT £452 = £2712	£2365 + VAT £473 = £2838	☐	
2 day conference 29 Feb – 1 Mar	£1305 + VAT £261 = £1566	£1450 + VAT £290 = £1740	£1525+ VAT £305 = £1830	£1595 + VAT £319 = £1914	☐	
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