



2nd World Congress on Biosimilars
10 June 2010 - Paris, France

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Recent Advances in Anemia, Oncology, Thrombosis, Neurology and Virology

A Slow Rising Wave or a Storm?

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Establish Solutions to Developmental and Strategic Issues for
Pharma Biotech Manufacturers

Provide the Pharmacologic and Medical Knowledge to Physicians becoming fully aware
about Mains Challenge and Outcomes for their daily activity

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On behalf of the Scientific Committee, we are pleased to announce the organization of the **2nd Biosimilars Congress** which will be held the **10th June 2010** in **Paris**.

Within the next two years, pharma market forecasts predict that **biopharmaceuticals will amount to more than 50% of newly approved medicines**. In addition to a growing market share, a substantial number of major biotechnology based drugs (rhu-EPO, Darbepoetin alfa, monoclonal antibodies....) will come off patent and enable the development of new biosimilar products. US'governance aims to set up specific guidelines for Biosimilars (F.O.B : Follow On Biologic) : this new scenario provides **opportunities for companies considering biosimilar as a priority for growing in pharmaceutical market**.

While this facilitates a great range of business opportunities, **biosimilar manufacturers** face high economic risk and need **to come up with an innovative business models**. In addition, it is crucial for them **to ensure that their R&D and production processes guarantee safety and efficacy of their products**. As some regulatory issues like interchangeability have not been resolved, manufacturers are particularly forced to come up with a **strong and innovative marketing strategy** convincing physicians and handling pricing as well as reimbursement issues effectively with regulatory authorities.

The 1st annual Biosimilars conference provided **insights on** :

- Biosimilar market (rhu-GH, rhu-EPO, GCSF, Insuline et analogues, HBPM)
- The successful strategy for the different actors through Epoetin alfa's biosimilar experience
- The EMEA guidelines and the French national scientific society position

The aims Biosimilars 2010 are to :

-Establish solutions to both developmental and strategic issues for pharma biotech manufacturers
-Provide the pharmacologic and medical knowledge to physicians becoming fully aware about main challenges and outcomes for their daily activity through lecture and case study driven presentations from leading pharma biotech manufacturers and relevant point of view from expert in their area.

This event will provide best practice solutions to help the main actors to resolve their existing and upcoming challenges in this market.

A series of interactive **roundtable discussions** will follow each lecture.

Scientific Committee & Speakers:

Dr A. D'Andon, Chef du Service Evaluation des Médicaments, Haute Autorité de Santé, Paris, France

Dr I. Macdougall, Consultant Nephrologist, Renal Unit, King's College Hospital, London, UK

Pr B. Polack, CHU de Grenoble, Grenoble, France

Dr M. Pavlovic, Responsable des avis scientifiques, DEMEB-AFSSAPS, Paris, France

Dr J-Y. Lecotonnec, CEO, Triskel, Geneva, Switzerland

Dr P-E Gérard, Directeur, Antares Consulting, Paris, France

Mr J.W. Choi, Director of Biology, POLYETHERICS, UK

Dr F. Lawny, Vice President Biotechnology, Triskel Integrated Services, Geneva, Switzerland

Mrs E. Berthet, Cabinet Armengaud Guerlain, Paris, France

Dr. A. Haselbeck, Roche Pharma Research, Germany

Please find hereafter the **program**.

We look forward to welcoming you in Paris for this particular event.

Dr Marvin Edeas
Chairman of the Organizing Committee

Biosimilars 2010 Scientific Program

June 10, 2010 – Paris, France

8H30 Registration

9H00 **Opening remarks from the Chair**

Dr A. D'Andon, Chef du Service Evaluation des Médicaments, Haute Autorité de Santé, Paris, France

9H15 **Evaluating the Biosimilars Market/Developing a biosimilar product in a regulated market**

Key-note session:

- Reason of generic companies (TEVA, Ratiopharm, Sandoz....) and new players (Novartis, GSK, Sanofi synthelabo, MSD....)
- Pursuit of biosimilar market?
- What are the key factors of success?
- Who are the potential players?
- Why physician are reluctant to adopt this new class of biotech?
- Main challenges to face for the actors?
- How do regulations impact portfolio development and market approval ?
- Factors driving the biosimilars market? Establishing product development strategies ?
- Implementing successful business models for follow-on biological medicines ?
- Highly innovative marketing strategies and implementation approaches?
- Considering quality and cost when developing biosimilars

Mr P-E. Gérard, Directeur, Antares Consulting, Paris, France

9H45 – 11H40

Session : Exploring R&D challenges

9H50 **Biosimilars: an analysis of successes and failures. What makes a successful biosimilars application?**

- Presentation of some practical cases
- Successful parameters

Dr. J-Y. Lecotonne, CEO, Triskel, Geneva, Switzerland

10H20 COFFEE BREAK

10h50 **Half-life modification and superior biosimilars**

- Unmodified biosimilars and how the market moved on: e.g. Interferon alpha vs. PEGylated molecules
- Outlining the need for site-specific modification of the protein
- Assessing the potential for an improved molecule with improved properties
- Examples of generic proteins with half-life modification

Dr J.W. Choi, Director of Biology, POLYTHERICS, UK

11h20 **Exploring the 2nd generation of biosimilars : mythe or reality?**

- Assessing biosimilar antibodies as the 2nd generation of follow-on protein products: new opportunities as therapeutic antibodies come off patents? Outlining the process of developing antibody biosimilars? Specific technical issues concerning monoclonal antibodies? Clarifying issues with clinical proof of similarity? Discussing strategic issues and understanding feasibility?
- Is the framework for biosimilars in Europe applicable to monoclonal antibodies? Current experience with biosimilars? Challenges for biosimilar antibodies? Future perspectives in the EU?

Dr F. Lawny, Vice President Biotechnology, Triskel Integrated Services, Geneva, Switzerland

11h50 **Overcoming regulatory and Intellectual Proprieties hurdles. Patents, patent term extensions and data exclusivity: opportunities for biosimilars?**

- How to make optimal use of "composition of matter" patents and "life cycle" patents
- Clarifying the IP implications of launching a biosimilar
- Data exclusivity, patent term extensions and new EU legislation on biosimilars
- Impact of the stringent regulatory regime involved in bringing biosimilars to market on your patent strategy

Mme E. Berthet, Cabinet Armengaud Guerlain, Paris, France

12h20 **Discussion**

12H30 LUNCH

14H00 Regulatory requirements for monoclonal antibody biosimilars:

- Quality Criteria
- Immunogenicity

Dr A. Haselbeck, Roche Pharma Research, Germany

14h30 Implementing successful business models for follow-on biological medicines of epoetin.

Dr I. Macdougall, Consultant Nephrologist, Renal Unit, King's College Hospital, London, UK

15H00 G-CSF and epoetin alfa in oncology: experience from the recent launch

Pr B. Polack, CHU de Grenoble, Grenoble, France

15H30: COFFEE BREAK

16H00 Heparine guidelines: from guideline to clinical practice

Dr M. Pavlovic, Responsable des avis scientifiques, DEMEB-AFSSAPS, Paris, France

16H30 Closing remarks from the Chair and close of day

For more information :

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