15th Biosimilars Congregation 2021

#VIbsc

"Uniting industry leaders to analyse advanced commercial developments & to identify successful strategies of Biosimilars"

23rd & 24th June 2021, Virtual Conference (Time Zone - BST)

AGENDA AT A GLANCE

Key Speakers Include

CLAUDIA LOUATI
Policy Advisor
FDA

FREDRIK SUNDBERG
Global Director, Strategic Technology Partnership, Cytiva (Formerly GE Life Sciences)

RAJESH DESIKAN
Vice President & Head, US Marketing, Oncology & Immunology Biosimilars
Fresenius - Kabi

JULIE MARECHAL JAMIL
Director Biosimilar Policy & Science
Medicines for Europe

MATTHEW TURNER
Senior Director Government Affairs and Policy Biosimilars Europe, Asia, Latam & Canada, Fresenius Kabi

CECIL NICK
Vice President
Parexel

ANNA AILLERIE
Brand Management Lead, Europe
Dr Reddy's Laboratories SA

MIGUEL NAVARRETE OLMEDO
Hospital & Biosimilars Commercial Director
STADA Arzneimittel

LOUIS BOON
CSO
Polpharma Biologics

HANMANT BARKATE
Vice President & Head Medical Services (India, MEA), Glenmark

SWEETY MATHEW
Regulatory Affairs
Biocon

MARTA BALDRIGHI
Policy & Science Officer
Medicines for Europe

NIKLAS EKMAN
Head of the Biological Section, Finnish Medicines Agency (Vice-Chair of the Biosimilar Working Party (BMWP), EMA)

OMAR ALI
Pharmacist Consultant
QIPP Adviser Payer Network

RENE ANOUR
Senior Clinical Expert/Head of National Scientific Advice, Austrian Medicines & Medical Devices Agency (AGES)

BER OOMEN
Executive Director, ESNO (European Specialist Nurses Organisations)

MICHEL MIKHAIL
International Expert in Biosimilars
Global Expert in Regulatory Affairs

LENNEKE DE WINTER
Senior Scientist USP
Polpharma Biologics

JAAP WIELING
CSO
BiosanaPharma

RICHARD EASTON
Technical Director -Structural Analysis
BioPharmaSpec

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Senior Director Delivery Systems
Ypsomed

ANDREAU SOLDEVILA
Founder & CEO
Syna Therapeutics

INGRID SCHWARZENBERGER
Senior Regulatory Consultant, Independent Consultant (Former Head Global Regulatory Policy, Sandoz)

BERT THOMAS
Senior VP, Business Development
Bio -Thera Solutions

SANDY EISEN
Chief Medical Officer
Frontline Pharma Consulting Ltd

ZIQUN HAN
Director
Zen Medical Science

MARIE MANLEY
Partner, Head of the UK Life Sciences
Sidley Austin

ALEXANDER ROUSSANOV
Life Sciences Regulatory & Privacy Lawyer
Arnold & Porter

ROBERT A. JOHNSTONE
Board Member
International Alliance of Patients Organisations

JOHAN DE MUNTER
Assistant Nurse Manager Cancer Center
University Hospital Ghent, President,
European Oncology Nursing Society

MARC MARTENS
Partner
Bird & Bird

Plus more COMING SOON.....

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CONFERENCE INTRODUCTION

Global biosimilars market size is expected to grow from USD 35.7 billion by 2025 from USD 11.8 billion in 2020, at a CAGR of 24.7%. This industry is experiencing significant growth due to the rising incidence of chronic diseases and the increasing demand for biosimilars due to their cost-effectiveness.The growth in the market may be attributed to the cost-effectiveness of the biosimilars when compared to reference biologics coupled with the patent expiration of the many blockbuster biologic drugs. Increasing investment by the companies for the development of biosimilars will also be the key factor driving the market.According to a recent report, as many as nine drugs in the biologics category have either gone off patent or will do so by 2025. Their total revenue was $62 billionin 2018. This creates a major opportunity for their respective biosimilars. It is estimated that revenue of these biosimilars will grow by 24 per cent annually for seven years to $13.3 billion in 2025 in the US and Europe. That offers a big opportunity

Our 15thBiosimilars Congregation 2021 will provide insight into the current state of play in the EU and stimulate debate, in a multi-stakeholder setting, on the vital role of biosimilar medicines in the sustainability of healthcare systems. Beyond a comprehensive outlook of key European market access policies, our speakers will outline the key recent developments in regulatory science and regulatory policy in the EU and other international jurisdictions. Special emphasis will be placed on strengthening the link between regulators and medical communities as an essential basis for greater understanding and acceptance of biosimilar medicines. This Biosimilars conference will focus on multiple aspects of Biosimilar product development to successfully deliver safe, Biosimilar products to the market place. By attending this conference, you will gain a comprehensive outlook on the key issues surrounding Biosimilars. This event will provide an important platform for Biosimilars stakeholders to discuss and share best practices in furthering Biosimilars development.

It gives me great pleasure in welcoming all of you to the Virtue Insight's 15thBiosimilars Congregation 2021.

CERTIFICATION

E-Certificate of attendance would be provided to attendees on request, upon completion of conference

KEY THEMES

- Strategies for market access and expansionby identifying key changes and future projections
- Understanding the biosimilars opportunity for pharma companies
- Consequences of Brexit & this pandemic situation on Biosimilars
- Current Challenges and Opportunities for future- Strategies in developing Biosimilars
- A Clinician's Guide to Biosimilars in Oncology: understanding the Science of Extrapolation and Interchangeability
- Biosimilars – Pricing & Market access - Bringing it faster into market
- GMP, GCP, QC & R&D
- Current challenges and opportunities - strategies to develop Biosimilars
- Payer perspective on biologics and Biosimilars
- Biosimilar Interchangeability: The newest regulation
- Biosimilar - Physicians and Patients perspective
- CMC, Preclinical and clinical considerations for Biosimilars and Follow-on Biologics
- Impact of Technology
- Commercial landscape & market access for Biosimilars: Predicts to prepare for a successful tomorrow
- Hear case studieson biosimilars drug development from pre-clinical to clinical and the various testing required such as immunogenicity and bio-similarity tests
- Research-based industry Biosimilar strategies
- Considerations for the analytical similarity assessments when designing a Biosimilar development program
- Determining the right investments & potential returns from Biosimilars
- Latest developments in regulation to increase speed of entry and compliance
- Future of next generation biosimilars
- Be part of a major networking opportunity

WHO SHOULD ATTEND

CSOs, CMOs, Vice Presidents, Presidents, Heads, Directors, Team Leaders, and Senior Scientists from the following roles:

Biopharmaceuticals/ Biotherapeutics, Follow on Biologics/Follow on Proteins/Biosimilars, Biologics/Biotechnology/ Biogenerics, Legal Affairs, Intellectual Property, Health Economics, Pricing and Reimbursement, Clinical Immunology, Principal Scientist, Chief Scientific Officer, Process Control and Analytical Technologies, Analytical Characterisation, Regulatory Compliance, Pharmacovigilance, Drug Safety & Risk Management, Quality Affairs/ Quality Control, New Product Development, Process Science, Portfolio Management, Research & Development, Business Development, Business Operations, Scientific Affairs, Commercial Affairs, Marketing

WHY SHOULD YOU ATTEND

Get more from the event, enjoy and make the best out of our **dedicated networking drinks time, meet the leading international vendors** showcasing the products of tomorrow in the co-located exhibition. **Expand your knowledge** of the latest business models and strategies in the high-level conference. Whether you are on the branded or generic side, you cannot afford to miss this opportunity to benchmark your tactics and strategies against the industry leaders who will be the first to traverse the pathway. Devise an immediate action plan for your biosimilar prosecution and litigation strategies in light of the barriers to entry, research and development costs, and regulatory hurdles, which are balanced against an enormous potential for increased profit margins.

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AGENDA AT A GLANCE

DAY ONE - 23rd June 2021

09:30 – Welcome Address & Virtual Conference Platform Instructions

MARKET OVERVIEW & ANALYSIS

09:40 – The biosimilar business case - A Growth formula for generics biosimilars

- Generics and Biosimilars: Industrial Strategy
- Globalization of Biosimilars
- GMP, GCP, QC & R&D
- Innovation and Technology for Biosimilar Development
- Licensing of biosimilars

PAYER'S PERSPECTIVE

10:20 – Biosimilars – Bringing it into the market quickly

- Strategies in overcoming obstacles in Biosimilar development
- Effective strategies for product design
- How Payers are aligning biosimilars?
- Global impact of biosimilars over generics
- Requirements for product development program
- Bridging the 'uncertainty gap' between payers & pharma - the shifting paradigm
- What to expect in the next 2 years?

OMAR ALI
Pharmacist Consultant
QIPP Adviser Payer Network

11:00 - Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

11:20 – Keynote Panel Discussion: Understanding the biosimilars opportunity for pharma companies

- Latest developments, Trends and Future of Biosimilars
- Looking at sustaining growth through pandemic
- Current Challenges and Research trends in Biosimilars & Biologics
- Issues to overcome to increase uptake of biosimilars
- Generate enough interest and enthusiasm for biosimilars
- Lack of stakeholder confidence – what does this lead to?

Moderator:

LOUIS BOON
CSO
Polpharma Biologics

Panellists:

CLAUDIA LOUATI
Policy Advisor
FDA

JULIE MARECHAL JAMIL
Director Biosimilar Policy & Science
Medicines for Europe

MATTHEW TURNER
Senior Director Government Affairs and Policy Biosimilars Europe, Asia, Latam & Canada, Fresenius Kabi

RENE ANOUR
Senior Clinical Expert/Head of National Scientific Advice
Austrian Medicines & Medical Devices Agency (AGES)

JOHAN DE MUNTER
Assistant Nurse Manager Cancer Center University Hospital Ghent**, President,** European Oncology Nursing Society

SANDY EISEN
Chief Medical Officer
Frontline Pharma Consulting Ltd

12:00 – Biosimilars, education and communication an essential for impact

The presentation will provide the background on the development of the Specialist Nurses Guide on biosimilar completed in 2019 after with a team of 7 Specialist Nurses and experts. This year 2021 enough relevance shows that it's time to scale up and give the guide an update with experienced overtime from health domains. The revision of the guide is of high relevance as overtime we have learned from COVID that fragmentation of knowledge and narratives causes confusion and at the end relapse of treatment and overall, switch management is always sensitive to non-adherence. The original expert group is extended with specialist from Croatia, Poland, and Portugal. This focus group will have a long-term structure and contribute not only to the second guide but also engage in activities such as events, webinars, meeting and contribute to a book on this topic in the series of Principle of Speciality Nursing under Springer Nature publications.

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DAY ONE - 23rd June 2021

BER OOMEN
Executive Director
ESNO (European Specialist Nurses Organisations)

12:40 - Networking luncheon

PATIENT'S PERSPECTIVE

13:50 – Analysing Physicians and Patients perspective

- National and International developments in biosimilar medicines
- Physicians education - Challenges
- Importance of Physician and Patients inputs to shape the international standards for biosimilars

MARTA BALDRIGHI
Policy & Science Officer
Medicines for Europe

14:30 – Reducing time to market: Fast track process development towards biosimilarity

- Accelerated high-titer cell line generation
- Upstream process modulation to obtain biosimilarity
- Biosimilar cell line portfolio for out-licensing

LENNEKE DE WINTER
Senior Scientist USP
Polpharma Biologics

15:10 – Afternoon Tea/Coffee

15:30 – Biosimilars in the context of public procurements in Europe – How compatible are these regulatory frameworks?

- Main principles and objectives of resp. the public procurement framework and of the regulatory framework applicable to biosimilars
- How free are contracting authorities in defining the subject matter of the contract ?
- Lack of – or limited – switching and interchangeability between biosimilars and exclusivity of supply.
- Challenges and obstacles in the light of case law and relevant cases
- What Strategies for biosimilar companies?

MARC MARTENS
Partner
Bird & Bird

COMMERCIALISATION & MARKET ACCESS

16:10 - Panel Discussion: Commercial landscape & market access for Biosimilars: Predicts to prepare for a successful tomorrow

- Comparison of US/EU biosimilar developments, policies and guidelines
- The impact of Biosimilars on the competitive landscape of biological products
- Challenges and obstacles faced by manufacturers in developing biosimilars
- Bringing the next generation of Biosimilars to the market
- Ensuring market access and reimbursement
- Evidence generation will be the key to future success
- Stakeholders approach in successfully bringing Biosimilars to the market

Moderator:

RAJESH DESIKAN
Vice President & Head, US Marketing, Oncology & Immunology Biosimilars, Fresenius - Kabi

Panellists:

ROBERT A. JOHNSTONE
Board Member
International Alliance of Patients Organisations

MIGUEL NAVARRETE OLMEDO
Hospital & Biosimilars Commercial Director
STADA Arzneimittel

BERT THOMAS
Senior VP, Business Development
Bio -Thera Solutions

ANNA AILLERIE
Brand Management Lead, Europe
Dr Reddy's Laboratories SA

MICHEL MIKHAIL
International Expert in Biosimilars
Global Expert in Regulatory Affairs

17:00 – End of Day 1 of conference.

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DAY TWO - 24th June 2021

09:30 – Welcome Address & Virtual Conference Platform Instructions

MANUFACTURING

09:40 – Overcoming Development Challenges for Biosimilars with Effective Bioprocessing and Analytics Quality by Design

- Current market and manufacturing challenges
- Cost-effective manufacturing approaches, quality-by-design and rapid quality control
- Novel analytics and regulatory strategies for bringing next generation Biosimilars to market

FREDRIK SUNDBERG
Global Director, Strategic Technology Partnership
Cytiva (Formerly GE Life Sciences)

10:20 – Clinical stage development of Mab biosimilars manufactured with fully continuous manufacturing

- Innovative manufacturing technologies
- Small footprint, high yields, low COGs
- First biosimilar completed phase I successfully

JAAP WIELING
CSO
BiosanaPharma

11:00 – Morning Coffee/Tea & Discussion

CLINICAL

11:20 – Clinical Data Requirements for Biosimilars: Have the regulators got it right?

- Residual uncertainty after demonstrating similarity at the structural and biological activity level
- Are studies in patients needed?
- What concerned are addressed by patient data
- The position of different regulatory agencies

CECIL NICK
Vice President
Parexel

12:00 – Topic TBC

RICHARD EASTON
Technical Director -Structural Analysis
BioPharmaSpec

12:30 - Networking luncheon

CLINICAL

13:50 – A Clinician's Guide to Biosimilars in Oncology: Understanding the Science of Extrapolation and Interchangeability

HANMANT BARKATE
Vice President & Head Medical Services (India, MEA)
Glenmark

14:30 – Leanbio capabilities and pipeline

- Lean Development for Biosimilars
- Lean bioproduction
- Cost effective CMC development
- Reduced non clinical and clinical program

ANDREAU SOLDEVILA
Founder & CEO
Syna Therapeutics

15:10 – Afternoon Tea/Coffee

15:30 – Self-injection devices for biosimilars – overview and market trends

- Introduction to devices for self injection with market overview
- Particular needs for the biosimilar area including IP aspects
- Recent trends from the market place 1 – larger volumes
- Recent trends from the market place 2 – carbon neutrality and renewable materials

JAKOB LANGE
Senior Director Delivery Systems
Ypsomed

DAY TWO - 24th June 2021

REGULATION OVERVIEW & UPDATE

16:10 - Panel Discussion: The developing regulatory framework in advanced and developing markets

- Market and regulatory developments in the Europe and globally
- Predicting the post Brexit changes in biosimilars regulation in UK
- EMA's act on switching & interchangeability?
- How regulators, payers and policy makers take initiatives to make healthcare more sustainable
- Collaboration with HTA's for patients benefit
- CMC regulatory considerations for Biosimilar products development
- Regulatory changes necessary to maximize biosimilars potential
- The way forward

Moderator:

LOUIS BOON
CSO
Polpharma Biologics

Panellists:

INGRID SCHWARZENBERGER
Senior Regulatory Consultant, Independent Consultant
(Former Head Global Regulatory Policy, Sandoz)

NIKLAS EKMAN
Head of the Biological Section, Finnish Medicines Agency (Vice-Chair of the Biosimilar Working Party (BMWP), EMA)

SWEETY MATHEW
Regulatory Affairs
Biocon

ZIQUN HAN
Director
Zen Medical Science

MARIE MANLEY
Partner, Head of the UK Life Sciences
Sidley Austin

ALEXANDER ROUSSANOV
Life Sciences Regulatory & Privacy Lawyer
Arnold & Porter

16:50 - End of conference

FOR SPONSORSHIP OPPORTUNITIES:-

Sponsorship or exhibition is the best way to speed network with decision makers. The world leader speakers in our conferences attract niche delegates from all over the world. This would be a wonderful opportunity to reach the right audience and save money and time on all your other advertising gimmicks. To give you an advertising edge we constantly update the industry pioneers via emails/news letter about the event and advertise the event via different forms of media.

Sponsorship Enquires - info.uk@virtueinsight.com

FOR DELEGATE REGISTRATIONS:-

Our potent conference agenda delivering the latest information and the world class leaders as speakers attract delegates to attend from around the world. We aim for our attendees to be equipped with knowledge of latest developments & enable them to network with the industry key personnel.

Delegate Registration - info.uk@virtueinsight.com

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REGISTER ONLINE :

Link : https://www.virtueinsight.com/pharma/15th-Biosimilars-Congregation-2021-Virtual-Conference/products/

For Multiple Bookings - Photocopy this form and send it to info.uk@virtueinsight.com

Delegate Details:

Title Mr ☐ Mrs ☐ Ms ☐ Dr ☐

First Name

Surname

Company

Position

Address

Pincode

Telephone

Fax

Email

How to Pay
(Choose one of the following payment options)

RESERVATION PRICING:

EARLY BIRD PRICE

1 Delegate @ £300 +VAT (Valid Till 17th May 2021)

3 Delegates @ £700 +VAT (Valid Till 17th May 2021)

STANDARD RATE

1 Delegate @ £500 +VAT (Valid From 18th May 2021)

3 Delegates @ £1200 +VAT (Valid From 18th May 2021)

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CERTIFICATION

E-Certificate of attendance would be provided to attendees on request, upon completion of conference

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TERMS AND CONDITIONS:

Payment terms: Virtue Insight requires the full amount to be paid before the conference. We may refuse entry to delegates who have not paid their invoice in full.

Cancellations: Delegates and vendors are subject to the following charges and refunds upon withdrawal or cancellation between 2-3 month's prior 75% cancellation fee/ 25% refund. Less than 2 months prior to the event Full cancellation fee / No refund.

Administration Fee: If you cancel your participation (once confirmed) and haven't paid the attendance fee you will be liable to pay an administration fee of £200

Substitutions/Name Change: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. This can be done at no extra cost.

Video : If you cannot attend the conference, you can still purchase the Video of the virtual conferences for £300.

Indemnity: Virtue Insight reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of Virtue Insight. If such a situation arises, we will reschedule the event.

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