Biosimilar Market Access and Commercialization Strategies Summit

Date : Sep 18, 2017 - 12:30 PM - Sep 19, 03:30 PM

Event URL : http://www.nyeventslist.com/events/biosimilar-market-access-and-commercialization-strategies-summit-aug-2017

Organizer : ExL Events

Venue : The Westin Boston Waterfront

Location : 425 Summer Street,
Boston, MA, US, ZIP: 02210

The FDA's approval of the first wave of biosimilars cleared the way for manufacturers to make lower-cost versions of expensive biologic drugs, saving patients money and improving access to important medications. There is a significant market opportunity ahead for biosimilar drugmakers; by 2020, leading biologic medicines worth more than $80 billion global annual sales will lose their patent protections, and biosimilars is the largest area for potential growth in the biotech sector. But with great rewards, there are also great risks that must be considered. In contrast to Europe, this is still an uncharted territory for the US market, and barriers to market access are not as low as they seem to be. From FDA approval to pricing and marketing strategies, there are risks and financial uncertainties. Therefore, the industry needs to know how to best address those challenges and optimize the biosimilar launch process.

Whether you are exploring your chances of tapping into the competitive biosimilars marketplace or are an expert in the field, the Biosimilar Market Access and Commercialization Strategies Summit will provide detailed presentations, intensive case studies and collaborative panel discussions relevant to your interests. Our talented faculty will address everything from navigating evolving regulations, analyzing optimal pricing models, accelerating market access strategies, and executing strategic decisions to mitigate risk and build for commercial success. In addition, designated lunches and networking breaks will enhance the exchange of knowledge and foster future business partnerships.

Featured Speakers Include:

Bruce Leicher
Senior Vice President and General Counsel
MOMENTA PHARMACEUTICALS

Chrys Kokino
Head Global Biologics Commercial
MYLAN

Rakesh Dixit
Vice President, R&D, Global Head, Biologics Safety Assessment
MEDIMMUNE, ASTRAZENECA GROUP

Ambrose Carrejo, Pharm.D.
National Pharmaceutical Contracting and Strategies Leader
KAISER PERMANENTE

Ashish Dugar
Officer & Vice President, Commercial Development
INTRA-CELLULAR THERAPIES

Molly Burich
Associate Director Public Policy
BOEHRINGER INGELHEIM

Top Five Reasons to Attend

1. Explore factors to consider before developing biosimilars — improve your chances on the road to approval and commercial success
2. Hear best practices and case studies for a successful biosimilar product strategy from its conception to execution
3. Stay up to date with FDA guidances and other regulatory guidelines and join the debate on nonproprietary naming of biological and biosimilar products
4. Navigate biosimilar policies, regulations and compliance issues under the new administration
5. Network with leaders in the industry and get tips on how to manage payer and provider considerations for market entry, engage with patients, and stay competitive

Who Should Attend

This conference is designed for biotech professionals responsible for:

- Biosimilars
- Biologics/Biotechnology/Biogenerics
- Biopharmaceuticals/Biotherapeutics
- Market Access Commercialization
- Marketing and Sales
- Strategic/Corporate Planning
- Pricing and Reimbursement
- HEOR and Outcomes Research
- Legal Affairs
- Intellectual Property
- Medical Affairs
- Manufacturing/Bioprocesses
- Clinical Affairs/Operations/Development
- Regulatory Affairs
- Medical Science Liaisons
- R&D
- Quality Control/Assurance

This event is also of interest to:

- CROs/CMOs/CMDOs
- Law Firms
- API Manufacturers
- Distributors
- Consulting Companies
- Market Access Providers
- Licensing Services
- Distribution and Logistics Services
- Packaging and Labeling Companies
- Preclinical/Nonclinical/Analytical Development Research Organizations

Day One

Monday, September 18
PRE-CONFERENCE WORKSHOP

8:15AM – 9:00AM

Registration and Continental Breakfast for Workshop Participants

9:00AM – 12:00PM

WORKSHOP: UNCOVER MARKET ACCESS OF BIOSIMILARS IN THE U.S. MARKET

While the biosimilar market continues to develop, much remains unanswered to ensure the commercial success of biosimilars in the United States. It is essential for manufacturers and product innovators to understand the approval pathways and familiarize themselves with the major issues surrounding market access and evaluation of biosimilars.

This workshop will help stakeholders identify key issues related to the U.S. biosimilar landscape and review effective strategies for market access.

Commercialization of Biosimilars: Navigating the Crossroads Between Business Development, Product Development, and Strategic Portfolio Management

- Analyze the issues, challenges and impacts of market access unknowns for biosimilars in the U.S. market
- Learn best practices for when to start/update market analysis for a new biosimilar program
- Implement data–driven rationale for biosimilar pipeline
- Discuss common pitfalls and realistic timelines in designing a biosimilar program

Pricing and Naming Considerations for Biosimilar Pipelines

- Review the topics to consider when developing biosimilar pricing strategies
- Examine the current dialog over biosimilar naming

Kristi Sarno, Senior Consultant, Latham BioPharm Group; Former Director Business Development, PFENEX, INC.

There will be a half–hour networking break at 10:00.

12:00PM – 12:30PM

Luncheon for Workshop Participants

MAIN CONFERENCE

12:30PM – 1:00PM

Main Conference Registration

1:00PM – 1:45PM

Chairperson's Welcome And Opening Remarks
John Coelho, Global Medical Strategy Leader, MERCK

1:45PM – 2:30PM

KEYNOTE: UNCOVER EMERGING TRENDS AND THE FUTURE OF BIOSIMILAR DRUG MARKET IN THE UNITED STATES
Chrys Kokino, Head Global Biologics Commercial, MYLAN

2:30PM – 3:15PM

ANALYZE THE BIOSIMILARS PIPELINE AND THE U.S. MARKET EVOLUTION
Ashish Dugar, Officer & Vice-President, Commercial Development, INTRA-CELLULAR THERAPIES

3:15PM – 3:45PM

Networking Break

3:45PM – 4:30PM

PANEL: REVIEW REGULATORY STRATEGIES AND INTERACT EFFECTIVELY WITH THE FDA
Bruce Leicher, Senior Vice President and General Counsel, MOMENTA PHARMACEUTICALS
Jennifer Horonjeff, Founder, Savvy Cooperative; Officer, Patient-Centered Outcomes Research, Columbia University Medical Center; Member of the Arthritis Advisory Committee and Consumer Representative, FDA

4:30PM – 5:15PM

Economics Impacts of Biosimilars
Joseph P. Fuhr, Adjunct Faculty, THOMAS JEFFERSON UNIVERSITY COLLEGE OF POPULATION HEALTH; Professor Emeritus of Economics, Widener University

5:15PM –

Day One - Closing Remarks

Call our call center at the number below or email marilyn.turner(a) nyeventslist.com for registrations or additional information about this event!

Day Two

Tuesday, September 19

8:15AM – 9:00AM

Registration and Continental Breakfast

9:00AM – 9:15AM

Chairperson's Recap of Day One
John Coelho, Global Medical Strategy Leader, MERCK

9:15AM – 10:00AM

THE INTERCHANGEABILITY GUIDANCE AND THE OPPORTUNITY AND EFFICIENT APPROVAL OF INTERCHANGEABLE BIOLOGICS
Bruce Leicher, Senior Vice President and General Counsel, MOMENTA PHARMACEUTICALS

10:00AM – 10:45AM

CASE STUDY: KAISER PERMANENTE'S BIOSIMILAR EXPERIENCE
Ambrose Carrejo, Pharm.D., National Pharmaceutical Contracting and Strategies Leader, KAISER PERMANENTE

10:45AM – 11:15AM

Networking Break

11:15AM – 12:00PM

BENCHMARK COMPLEX FACTORS TO DECIDE BETWEEN BIOBETTER VERSUS BIOSIMILAR DEVELOPMENT OPTIONS
Rakesh Dixit, Vice President, R&D, Global Head, Biologics Safety Assessment, MEDIMMUNE, ASTRAZENECA GROUP

12:00PM – 12:45PM

REVIEW THE REGULATORY IMPACT OF BIOSIMILAR MARKET ENTRY: HOW GUIDANCE AND LEGISLATION IMPACTS APPROACH TO MARKET ENTRY
Patrick Lucy, PFENEX Interim CEO, President and Secretary, and Chief Business Officer, PFENEX

12:45PM – 1:45PM

Luncheon

1:45PM – 2:30PM

DISCUSS REIMBURSEMENT CONSIDERATIONS FOR BIOSIMILARS
Molly Burich, Associate Director Public Policy, BOEHRINGER INGELHEIM

2:30PM – 3:15PM

UNDERSTAND THE IMPORTANCE OF PATIENT-CENTERED RESEARCH IN BIOSIMILAR DRUG DEVELOPMENT
Jennifer Horonjeff, Founder, Savvy Cooperative; Officer, Patient-Centered Outcomes Research, Columbia University Medical Center; Member of the Arthritis Advisory Committee and Consumer Representative, FDA

3:15PM –

Day Two – Summit Closing Remarks

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Event Categories : BUSINESS & MANAGEMENT CONFERENCES,