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DESIGN A SUCCESSFUL COMMERCIAL STRATEGY FOR ENTRY INTO THE U.S. BIOSIMILARS MARKET BY ENSURING APPROPRIATE PRICING, EDUCATION, AND VALUE PROPOSITION TO CUSTOMERS

FEBRUARY 23-24, 2016 • SHERATON PENTAGON CITY HOTEL • ARLINGTON, VA

FEATURED MANUFACTURER PERSPECTIVES:

Molly Burich
Associate Director, Public Policy – Biosimilars, Pipeline and Reimbursement
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC

Sue Naeyaert
Head, Global Pricing and Market Access Biosimilars
MERCK SERONO

Nicole C. Quon, PhD
Head, Global Payer Marketing and Market Development Biosimilars
BOEHRINGER INGELHEIM GBMH

Alex Waldron
Global Commercial Operations
EPIRUS PHARMACEUTICALS

PLUS!

Sally Howard, JD
Former Senior Advisor to the Commissioner
FDA

Elizabeth Jex, Esq.
Attorney Advisor, Office of Policy Planning
FTC

Alan Lyles
Henry A. Rosenberg Professor of Government, Business, and Nonprofit Partnerships
UNIVERSITY OF BALTIMORE

Katherine A. Macfarlane
Associate Professor of Law
UNIVERSITY OF IDAHO COLLEGE OF LAW
Patient Advocate
GLOBAL HEALTHY LIVING FOUNDATION

TOP REASONS TO ATTEND:

- Discuss pricing and reimbursement trends to best prepare for product launch
- Extract lessons from more developed biosimilar markets to design your U.S. strategy
- Identify effective means of educating the market on the value of biosimilars
- Gain clarity on the legal and regulatory landscape for biosimilars in the U.S.
- Engage with a diverse faculty of key decision makers to help inform commercial strategy

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Dear Colleague,

After some legal constraints, the U.S. biosimilar market officially opened up when the first biosimilar launched in September 2015. And now, many more biosimilars are lined up to go through the FDA's regulatory approval pathway. As the promise of biosimilars becomes a reality not just for manufacturers but for payers, providers, and patients, many questions that were once speculation are beginning to be answered.

Now is the time to hear from stakeholders across the value chain to design a market access strategy for biosimilars to ensure success well into the future. As the landscape continues to evolve, it is imperative to get a solid understanding of who the final decision makers will be; how to work with the various stakeholders to increase market access for biosimilars; and how it all comes back to product value, pricing, contracting, regulations, and legal constraints.

Join us February 23-24 to engage in a multi-stakeholder discussion around strategies for responding to regulatory and commercial challenges. Address the most important issues facing biosimilar products as they enter into the U.S. market, including:

- Pricing and reimbursement strategies to ensure commercial success
- Value communication and education for biosimilars to promote acceptance
- Formulary and post-market surveillance strategies for improving uptake
- Patient considerations and concerns regarding biosimilar usage
- Lessons learned from foreign biosimilar markets

I look forward to seeing you there!

Sincerely,

Sue Naeyaert

Sue Naeyaert
Head, Global Pricing and Market Access Biosimilars
MERCK SERONO
Chairperson, 2nd Annual Biosimilars Market Access Summit

WHO SHOULD ATTEND:

FROM BIOSIMILAR AND BIOLOGIC MANUFACTURERS

Vice Presidents and Directors of:

- Biosimilars
- Biologics
- Commercial Strategy
- Commercial Development
- Market Access
- Product Launch
- Pricing and Reimbursement
- Business Development
- Payer Marketing
- Competitive Intelligence
- National and Regional Accounts

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- Market Research Analysts
- Consultants specializing in Market Access and Product Launch

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DAY ONE – TUESDAY, FEBRUARY 23, 2016

7:30 am – 8:30 am

Summit Registration and Morning Coffee

8:30 am – 8:45 am

Chairperson's Welcome and Opening Remarks

Sue Naeyaert
Head, Global Pricing and Market Access Biosimilars
MERCK SERONO

8:45 am – 9:30 am

Explore Reimbursement and Pricing Considerations for Biosimilars

CMS confirmed its pricing design for biosimilars in fall 2015, setting the path for private payers and biosimilar companies to move forward.

- Understand how the reimbursement coding decision would impact biosimilar pricing
- Gain an overview of pricing and reimbursement trends for biosimilars to develop an effective commercial strategy

Molly Burich
Associate Director,
Public Policy – Biosimilars, Pipeline and Reimbursement
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC

Jonathan Dunn
Pharmaceutical Pricing and Market Access Executive

9:30 am – 10:15 am

Gain an Overview of the Current Regulatory Landscape Impacting Biosimilar Market Access Strategy

Review the current regulatory guidance on biosimilars and gain clarity on issues of standards for licensure, indication extrapolation, use of ex-U.S. data, naming, and substitution. Each issue impacts who is marketed to, what information can be communicated, and how to refer to your products once on the market.

- Dissect the FDA guidance on naming of biosimilars
- Consider the issues of similarity, interchangeability, and substitution
- Discuss the FDA's views on standards for licensure, including extrapolation across indications and use of ex-U.S. data

Sally Howard, JD
Former Senior Advisor to the Commissioner
FDA

Daniel Kracov
Partner and Co-Chair, FDA and Healthcare Practice Group
ARNOLD & PORTER

10:15 am – 10:45 am

Networking and Refreshment Break

10:45 am – 11:30 am

FTC Perspective: Ensure Fair Competition in the Biosimilar Market

Sandoz' Zarxio entered the market in September 2015, officially ushering in the biosimilar era in the U.S. From the unique perspective of the FTC, become familiar with the status of biosimilar competition in the U.S. and abroad.

- Explore the relevance of specialty drug trends on the biosimilar market
- Analyze the impact of the first biosimilar launch in the U.S.
- Identify what the European experience with biosimilars can tell us in regards to competition
- Discuss market challenges facing biosimilar competition in the U.S. related to naming, reimbursement, and market acceptance

Elizabeth Jex, Esq.
Attorney Advisor, Office of Policy Planning
FTC

11:30 am – 12:15 pm

Create a Robust Patient Services and Reimbursement Support Program for Biosimilar Products

Patient access to biosimilars depends on insurer policies, cost, and support services. Patient services and reimbursement programs, while staples at originator companies, must be tailored for the biosimilar market to be effective. It is important for biosimilar manufacturers to build patient support services and ensure their programs fit the needs of the biosimilar market.

- Understand the service requirements for biosimilars, as compared with other biologics and other drugs
- Identify best practices for design and implementation of support programs
- Assess the initiatives that need to be in place to break down patients' financial barriers to access
- Discuss the value of free product programs to promote patient access

Marissa Fuller, MHS
Senior Director
COVANCE MARKET ACCESS SERVICES

12:15 pm – 1:30 pm

Luncheon

1:30 pm – 2:15 pm

Hear a View of the Patient Community's Perception of the Promise and Potential of Biosimilars

Patients are key players in realizing uptake for biosimilars as they ultimately receive these products and endorse their usage. Each stakeholder group has a unique perspective and together they present the market reality for biosimilars and the obstacles that must be overcome for success. In this session, hear the viewpoints and backgrounds of this essential group and discuss key issues they identify when considering biosimilar use.

- Describe the physical, emotional, and financial toll biologics can have on patients and how biosimilars may be able to improve upon these experiences
- Identify patients' health concerns with respect to biosimilars
- Learn what measures biosimilar players can take to encourage uptake and what is expected of manufacturers
- Identify what needs to be done to promote full confidence in the biosimilar product class

Katherine A. Macfarlane
Associate Professor of Law
UNIVERSITY OF IDAHO COLLEGE OF LAW
Patient Advocate, **GLOBAL HEALTHY LIVING FOUNDATION**

Steve Marmaras
Director, State and National Advocacy
GLOBAL HEALTHY LIVING FOUNDATION

2:15 pm – 3:00 pm

Effectively Communicate the Value of Biosimilar Products to Raise Confidence in the Class

With the U.S. biosimilar market just now opening up, there is no exact precedent on how to effectively communicate the value of these products and the biosimilar class as a whole. Value communication is fundamental to a successful market access strategy and this session explores its intricacies in the biosimilar market.

- Learn what approaches large innovators are taking and whether smaller manufacturers should follow suit
- Explore whether price points are sufficient or if other determinants need to be articulated
- Determine ways to address or avoid confusion over naming and label constraints
- Identify long-term branding, promotion, and marketing investments that will have the most impact on commercial success

Alan Lyles
Henry A. Rosenberg Professor of Government, Business, and Nonprofit Partnerships
UNIVERSITY OF BALTIMORE

3:00 pm – 3:30 pm

Networking and Refreshment Break

3:30 pm – 4:15 pm

Identify Channels to Improve Biosimilar Acceptance in the Marketplace

There remains a gap between market expectations of biosimilars and manufacturers' realities that must be met to support market access. This session explores the key ingredients needed for preparing the market to commercialization of this unique class of products.

- Develop best practices for enhancing customer-facing channel interaction
- Prepare responses to potential hurdles by uncovering the risks and uncertainties felt by the market in this space
- Assess which services are necessary to be provided with product launch, including nursing services and reimbursement, to meet customer expectations

Alex Waldron
Global Commercial Operations
EPIRUS PHARMACEUTICALS

4:15 pm – 5:00 pm

Develop Strategic Partnerships for Global Biosimilar Business Development

Geographically, the market for biologics and biosimilars falls into three distinct clusters: the U.S., the other advanced economies (including Europe, Japan, and Canada), and the emerging markets. There has been much M&A activity in recent years; however, there have also been more than 4,000 new biotech companies entering the market within the first 30 years of the biotech industry, plus large pharmaceutical companies increasingly in-licensing and acquiring important portions of their pipeline from biotech.

- Identify the opportunities and considerations of strategic partnering to design a successful strategy
- Articulate the distinctions between partnerships across the U.S., other advanced economies, and emerging markets
- Understand the impact of increased licensing and acquisition of biotech products by larger pharmaceutical companies

Magdalena Leszczyniecka
President and CEO
STC BIOLOGICS

Leandro Mieravilla
Global Biosimilar Business Development Executive

5:00 pm – 6:00 pm

Cocktail and Networking Reception

DAY TWO – WEDNESDAY, FEBRUARY 24, 2016

7:30 am – 8:00 am

Morning Coffee

8:00 am – 8:15 am

Chairperson's Welcome and Review of Day One

Sue Naeyaert
Head, Global Pricing and Market Access Biosimilars
MERCK SERONO

8:15 am – 9:00 am

Part One: Identify Formulary and Post-Market Surveillance Strategies for Biosimilars and their Innovators

How payers decide to reimburse for biosimilar products has a clear impact on the commercial success of the market as a whole. The success of individual products also hinge on their inclusion on a payer's formulary.

- Hear considerations involved in the compilation of drug formularies with respect to biosimilar products
- Hear what payers are doing to support biosimilar uptake
- Explore the facets of the Pharmacy and Therapeutics discussion on biosimilars

Mary Jo Carden, RPh, JD
Vice President, Government and Pharmacy Affairs
ACADEMY OF MANAGED CARE PHARMACY

Part Two: Understand the Importance of Post-Marketing Surveillance of Biosimilar Products

Bernadette Eichelberger, PharmD
Program Director
BIOLOGICS AND BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM (BBCIC)

9:00 am – 9:45 am

Understand Private Payer Reimbursement Considerations for Biosimilars

A key question to the successful uptake of biosimilars in the U.S. is how health insurers will control access to these products. To better understand payers' views on biosimilars, a survey of commercial payer decisionmakers, was conducted with survey respondents representing over 100 million covered lives. The survey was designed to explore a variety of factors that may influence how payers manage biosimilars. Hear key findings from this survey and discuss their implications for market access for biosimilars.

- Gain insight into how commercial payers are covering and managing the first wave of U.S. biosimilars, as well as the resulting impact on patient access to competing reference products
- Discuss how payers' management approaches may evolve as more biosimilar versions of a product become available
- Compare the relative importance to payers of factors such as therapeutic area, type of FDA approval, interchangeability, and pricing
- Understand how CMS's recent coding and payment decisions for biosimilars could influence commercial payers' policies
- Identify the tools that payers can use to control access to biosimilars and reference products, and discuss key differences for medical benefit vs. pharmacy benefit coverage

John Carlsen, MHA
Vice President
COVANCE MARKET ACCESS SERVICES

9:45 am – 10:15 am

Networking and Refreshment Break

10:15 am – 11:00 am

CASE STUDIES: Leverage Global Experience to Optimize U.S. Biosimilar Adoption

While many countries have experience with biosimilars, the uptake has been quite varied. This session focuses on the regulatory, economic, and public policy frameworks for key foreign markets and discusses lessons learned that could be applied to promote U.S. market success.

- Explore the barriers and incentives for biosimilars in foreign markets
- Evaluate the impact of these market dynamics on biosimilars uptake
- Discuss how these insights could be applied to the U.S. biosimilars market

Nicole C. Quon, PhD
Head, Global Payer Marketing and Market Development Biosimilars
BOEHRINGER INGELHEIM GBMH

11:00 am – 11:45 am

Evaluate the Long-Term Implications of Your Market Access Strategy

Market access strategies differ for products entering into smaller, new markets from those entering into more established markets. As the U.S. market grows, biosimilar players must adapt their strategies for increased competition and upon a more solid foundation. Considerations to the number of players in the market, the efficiency of the drug for long-standing patients, and the pricing trends over time are all crucial to long-term success.

- Anticipate longer-term trends in delivery methods based upon the European experience
- Explore options for long-range strategies for a more developed U.S. market in 5-10 years

Molly McGlaughlin
Vice President, Business Development and Marketing North America
EIRGENIX, INC.

11:45 am

Close of Summit

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IN THIS PIVOTAL YEAR FOR BIOSIMILARS IN THE U.S.:

- Hear industry perspectives on CMS' stance regarding pricing and use of biosimilars
- Gain insight around the FDA's thinking of the nonproprietary naming of biological products
- Refine strategies following the first biosimilar launch in the U.S.

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