FDA releases Biosimilar Action Plan - Hear more at this year's Biosimilars USA conference

Following FDA's release of Biosimilar Action Plan, this year's Biosimilars USA conference promises to explore the developments in biosimilar drug development

Biosimilars USA 2018

LONDON, WATERLOO, UNITED KINGDOM, July 19, 2018 /EINPresswire.com/ -- As the world of biosimilars gains more traction and promise, and the FDA announces the release of a long-awaited Biosimilar Action Plan, SMi's 5th Annual Biosimilars USA Conference, taking place in New Jersey, USA on the 14th and 15th November 2018, aims to give crucial updates to biosimilar experts and scientific pioneers across the world in this rapidly evolving industry.

During a speech given this week in Washington, DC, FDA Commissioner Scott Gottlieb, MD, announced the release of the long-awaited Biosimilar Action Plan. The plan is designed to promote biosimilar competition in the US marketplace by addressing the following 4 key areas:

• Improving the efficiency of the biosimilar and interchangeable product development and approval process
• Maximizing scientific and regulatory clarity for the biosimilar product development community
• Developing effective communications to improve understanding of biosimilars among patients, providers, and payers
• Supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay market competition to follow-on products

"While less than 2% of Americans use biologics, they represent 40% of total spending on prescription drugs," said Gottlieb. "So, enabling a path to competition for biologics from biosimilars is a key to reducing costs and facilitating more innovation." [centerforbiosimilars.com]

Also in recent news were statements made by the chair of this year's two-day conference; Richard DiCicco, the chairman of Harvest Moon Pharmaceuticals USA. Richard expressed his views on Amgen, which he claims has the ability to take advantage of the unique dynamics and inefficiency of the US market as Mylan recently announced WAC for biosimilar Neulasta at $4,175/syringe and

Amgen set Neulasta's WAC at $6,231, and its ASP dropped to $4,453 in the July CMS report.

According to Richard, if Mylan's biosimilar ends up as a market failure, this suggests that the US market does not allow adoption of lower-priced drugs unless the US healthcare system adapts. With both timing and pricing pressure (and Amgen is ready to protect Neulasta with bundled contracts), Richard expects Mylan to quickly move toward conversations with payers, and commercial uptake of this biosimilar will depend upon negotiation success. Richard also states that whether this biosimilar is a success or a failure has larger implications for the total success or failure of the US biosimilar market.

This year's Biosimilars USA conference will provide delegates with the opportunity to hear from a selection of in-depth keynote addresses and case studies presented by top manufacturing and leading distributors of market-approved biosimilars, as they offer a unique insight into the areas of manufacturing, commercialization, device design, uptake, switching, interchangeability, and regulations.

The latest conference brochure, as well as other exclusive content including the full speaker line-up and an interview with expert speaker Hillel Cohen, Executive Director, Scientific Affairs, Sandoz Inc, are now available to download on the event website, where you can also register your place: www.biosimilars-usa.com/einpr

Interested in sponsoring, exhibiting or speaking at this event?
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Biosimilars USA
14th – 15th November 2018
Renaissance Woodbridge Hotel, 515 US Highway 1 South, Iselin, New Jersey, USA
www.biosimilars-usa.com/einpr

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