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Emerging biosimilars in the USA – *Quo vadis*?

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While the US biosimilar market has lagged behind Europe for almost a decade due to delays concerning the release of specific guidelines by the FDA, the market is poised for growth. Of the estimated size of $60 billion for the US biologics market in 2020, major products such as Lantus, Herceptin, Neulasta, Avastin, Rituxan, Remicade, and Humira will lose patent exclusivity thereby creating a significant market potential for biosimilars of these products in their respective therapeutic areas diabetes, cancer and autoimmune diseases like rheumatoid arthritis. This is expected to lead to the increased availability of lower priced treatment options for these conditions. Another wave of biologics will lose patent exclusivily between 2020 and 2025, potentially increasing the market size of biosimilars further. With an increased number of biosimilar options and a more well-defined regulatory pathway, US payers will strive to adapt to the changing market. US payers believe that biosimilars should be treated as low-cost branded products rather than generics, which can save the health care system billions of dollars by switching patients from originator drug products to biosimilars. This presentation will discuss the current status of the US biosimilar market, the leading developers of biosimilar, competition for both first and second wave biosimilars, influence of regulations on federal and state level on market entry, including stakeholder perceptions.

Biography

Melissa Law is the Senior Research Analyst at Technology Catalysts International, USA and is associated with TCI since 2011. She has completed her Postgraduation in Biotechnology from Georgetown University. Currently, she assists clients in identifying licensing and partnering opportunities in the consumer care and biologics industry. Her area of focus includes biosimilars, OTC medication, personal care, nutrition, and packaging.

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