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Developing biosimilars: Considerations, opportunities and challenges

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Biologic drugs have emerged as a major therapeutic class in the market. Currently, there are 4 biologics among the top ten best-selling drugs. It is estimated that by 2016, 7 of the top-ten-selling drugs will be biologics. With a significant number of biologic drugs losing patent protection in the coming years and the publication of the FDA guidance on the development of biosimilars, the drug industry is increasingly focusing on biosimilars as a major investment opportunity. In particular, the monoclonal antibody family of therapeutics has attracted a lot of attention partly due to their more mature manufacturing processes and near-term patent expirations on several blockbusters in this class. While the recent FDA guidance is helpful in defining a development path for biosimilar development, key considerations must be made in the context of the guidance and translated into executable development plans and milestones for a given biosimilar product of interest. Strategically important factors include manufacturing processes, analytical capabilities, and technical and regulatory know-how. Although the primary goal is to demonstrate there are no clinical meaningful differences between the proposed biological product and the reference product in terms of safety, purity and potency, gaining interchangeability and potential exclusivity is critical in ensuring commercial success. There are many challenges in developing biosimilars, the importance of technical know-how and practical execution will be discussed.

Biography

Ming Wang is Executive Director and heads Amgen's diabetes drug discovery function on two research sites. He also plays important roles in clinical development programs and licensing efforts. Prior to Amgen, Ming championed drug discovery programs and managed corporate partnerships in Parke-Davis, Pfizer and Pharmacia. Ming has served on many advisory boards and is a frequent speaker at scientific and drug discovery conferences. He has nearly 60 publications and a book entitled "Metabolic Syndrome: underlying mechanisms and drug therapies" (publisher; John Wiley & Sons, Inc.). Ming is also an adjunct faculty at UCSF Schools of Pharmacy and Medicine.

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