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5th European Biosimilars Congress

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Biosimilars in rheumatology practice: Where we stand?

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Biopharmaceuticals are biological medical products derived from cell culture or fermentation to produce therapeutic proteins that target pathogenic protein molecules by either neutralization or inhibition of their biologic hazards. Biosimilars on the other hand represent a form of biopharmaceuticals intended to be clinically equivalent end product yet unidentical to another existing biopharmaceutical. Reasons behind their being unidentical to an existing biologic are rather complex, however, many of such products are being increasingly investigated in the field of autoimmune diseases. The use of biosimilars has been linked to a 20-25% cutdown in therapeutic costs. With the increasing need for such product clinical development programs are being progressively updated to provide sufficient evidence for equivalent efficacy and comparability of safety and immunogenicity between candidate biosimilar and the reference biologic. Considering the latest therapeutic advent with the establishment of the treat to target strategy, the use of biosimilars in rheumatology practice seems tempting and deserves potential consideration with intense efforts.

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Regulatory update and overview of specific scientific issues for development and approval of biosimilars in US

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The passage of 2009 Biologics Price Competition and Innovation Act of 2009 (BPCI Act) in US established a regulatory pathway for the approval and marketing of biosimilars in US. FDA subsequently published a number of general guidance documents between 2012 and 2015 to provide guidelines to the industry on the regulatory process and clarifies the data requirements for the developments and approval of biosimilars. For the final approval of first biosimilar, Filgrastim, FDA also utilized the publication of advisory committee report to lay out the examples of regulatory and data requirements under current biosimilar law. Futhermore, the recent submission of a biosimilar application for Humira® to both EMA and US FDA also represented a milestone with far reaching implications to the field of biosimilar developments in US. Based on Dr. Wu's unique regulatory experience at FDA and recent interactions with various regularory agencies on the development of several biosimilar MAbs and therapeutical proteins, the presentation will cover the followings:

- An update on the current regulatory development in the US,
- Concept of step-wide approaches in demonstratiion of comparability as recommended by FDA
- The unique challenges of complex regulatory and scientific issues in US such as User Fees, consultation meetings, reference products, naming, interchangeability of biosimilars.
- Recommendations to overcome the challenges for the biosimilar product develoment in US.

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