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PEG-Modified biosimilars: Potential role in the emerging global biosimilar market

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The newly amended Public Health Service (PHS) Act clears the way for an abbreviated licensure pathway to "Biosimilars" or to "Interchangeable" with an FDA approved biological product. Now it is only a matter of time biosimilars hit the US, Japan and other world markets, if it isn't already. EU has several Biosimilars presently in the market. However, Biosimilars suffer the same clinical shortcomings as that of the original "innovator" molecules, such as short circulating half-life, immunogenicity and proteolytic degradation, among others.This is especially true for cytokines, hormones, growth factors and antibody fragments. These shortcomings could be circumvented by the application of the well-established and proven PEGylation technology to biosimilars. In this presentation, the rationale, and clinical development strategies including reasonable timelines are presented. In order to be attractive to the medical community and to be competitive in the market place, PEG-biosimilars must be safe, more potent, longer-acting and cost-effective compared to their corresponding innovator biomolecules.

Biography

Pascal Bailon is a retired Research Director from Hoffmann-La Roche, Inc., Nutley, NJ. He is the inventor and patent holder of the APIs of Pegasys® for the treatment of hepatitis C, Mircera®, for the treatment of renal anemia and the first ever Receptor-Affinity Chromatography for the purification of fully refolded and monomeric rIL-2 from inclusion bodies. He had published in prestigious journals, like Nature, Biotechnology, PNAS and Blood, among others. He had edited the book on Affinity Chromatography Methods and Protocols. He is the recipient of numerous awards for his scientific contributions.

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