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The end of biosimilars phase 3 clinical trials?

Most patients still have limited or no access to life-changing therapeutic proteins in the treatment of their cancer or autoimmune disorders; the current clinical development model of biosimilars is expensive and in most cases large phase 3 trials do not provide meaningful information on the clinical equivalence between biosimilars and reference compounds. At the same time, the development of orthogonal, state of the art analytical methods has enabled a better understanding of the structure and structure-function relationship of biotherapeutics. Hence, we suggest here that a solid CMC package, together with meaningful phase 1 studies will leave limited uncertainty on biosimilarity, that if needed can be addressed by post-approval long-term follow-up studies (post-approval studies, pharmacovigilance, real world evidence data and registries); We believe that this new approach may be more appropriate than 600-1000 patients phase 3 trials in assessing biosimilarity and therapeutic equivalence, under the condition that administered biosimilar given to individual patients can clearly be identified. Obviously, it will probably never be a "one size fits all" development model and an individualized, risk-based approach to biosimilar, developments will always have to be considered and discussed early with regulators.

Biography

Francois-Xavier Frapaise has over 30 years of international drug development, strategic planning and marketing experience at major pharmaceutical companies including Sanofi, Bayer, Boehringer, Merck and Abbott; he has hold multiple C-level positions (CSO,CMO,CEO) in different Pharmacos in the US and Europe. He is currently heading Clinical Development, Medical Affairs and Pharmacovigilance at Merck KGaA Biosimilars Division; he has extensive experience of biosimilars development (Boehringer-Ingelheim, Pfenex); He has been the CSO and SVP of Optimer, has served as the CEO of Asphelia Pharmaceuticals, Inc.VP R&D and Corporate Officer of TAP , CMO of Ocera Therapeutics, VP of Scientific Affairs at Abbott International , Head of Medical Affairs at Bayer Europe, Medical Director at Bayer France, VP of R&D at Delagrange, Head of Anti-thrombotics Strategic Marketing at Sanofi, Medical Director at Choay. Frapaise holds an MD degree from Faculté de Médecine Paris and is a INSEAD alumni. Frapaise holds an academic position at the Thrombosis Research Center at the Loyola Medical Center in Maywood (IL).

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