Abstract

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The end of Phase 3 clinical trials in biosimilars development?

FX Frapaise
F.-X. Frapaise Consulting, France

Abstract

Most patients still have limited or no access to life-changing therapeutic proteins in the treatment of their cancer or autoimmune disorders. The development of biosimilars is a complex and expensive undertaking, the more as what is called “reference compound” is often a moving target, these compounds manufacturing process experiencing multiple changes, some being significant. The current clinical development model of biosimilars is expensive, as it is based on large, comparative phase 3 trials that in most cases do not provide meaningful information on the clinical equivalence (efficacy/safety) of biosimilars and reference compounds. At the same time, the development of state-of-the-art orthogonal analytical methods has enabled a better understanding of the structure and structure-function relationship of biotherapeutics. Hence, we suggest here that a solid chemistry, manufacturing, and controls (CMC) package and meaningful phase 1 studies will leave limited uncertainty on biosimilarity, which can be addressed-if needed-by post-approval, long-term follow-up studies (post-approval studies, pharmacovigilance, real world evidence data and registries, and possibly new post-approval models to be developed). We believe that this new approach may be more appropriate than 600- to 1000-patient, phase 3 trials in assessing biosimilarity and therapeutic equivalence, under the condition that the administered biosimilar given to individual patients can be clearly identified. Obviously, there will probably never be a "one size fits all" development model, and an individualized, risk-based approach to biosimilar development will always have to be considered and discussed early with regulators.

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Biography

Francois-Xavier Frapaise, has over 35 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. Until recently ,he was heading Clinical Development, Medical Affairs and Pharmacovigilance at Merck KGaA Biosimilars Division; he has extensive experience of biosimilars development acquired at Boehringer-Ingelheim and Pfenex); he now runs a consulting business, based in Paris. 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 M.D. 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).

