Tim Demuth et al., J Bioanal Biomed 2017, 9:3(Suppl)
http://dx.doi.org/10.4172/1948-593X-C1-026

Development of Etanercept biosimilar Erelzi™

Tim Demuth, Antonio Da Silva, Martin Schiestl and **Cornelius Fritsch**
Sandoz Pharmaceuticals GmbH, Germany

GP2015 has been developed as a biosimilar to Enbrel® (etanercept) and was approved as Erelzi by US FDA in August 2016. Assessment of biosimilarity follows the totality-of-the-evidence concept taking into consideration physicochemical, biological, nonclinical and clinical data. Biosimilarity to the approved originator product is confirmed in a step-wise approach. Characterization of multiple originator batches was conducted over time followed by an iterative, target-directed development process to yield a product falling into the variability range of the originator. Biosimilarity between GP2015 and the originator was confirmed at analytical, functional, nonclinical, pharmacokinetic (PK) and clinical levels. Bioequivalence between GP2015 and the originator was assessed in PK studies in animals and healthy volunteers. To detect clinically meaningful differences between GP2015 and originator, efficacy, safety and immunogenicity was studied in patients with moderate to severe chronic plaque type psoriasis. This phase III confirmatory study assessed the Psoriasis Area and Severity Index response rate at weeks 12, 30 and 52. ErelziTM was developed at the same dosage and strength as the originator. Multiple analytical methods showed high similarity between GP2015 and the originator. The amino acid sequence was confirmed to be identical and protein folding was indistinguishable. In-vitro assays showed GP2015 and the originator had similar bioactivity. PK bioequivalence between GP2015 and the originator was established in nonclinical and human studies. The study in patients with psoriasis confirmed similar efficacy and safety and comparable immunogenicity in a highly sensitive indication. In all studies, no clinically meaningful differences between GP2015 and the originator were observed. Analytical, functional, nonclinical and clinical data provide comprehensive understanding of GP2015 and the originator and demonstrate a high level of similarity between the two substances in accordance with regulatory requirements. The totality of evidence of biosimilarity justifies the use of the biosimilar in the same indications as Enbrel® and was confirmed by FDA.

Biography

Tim Demuth, MD is a Clinical Development Unit Head at Sandoz Biopharma responsible for clinical strategy, and execution of biosimilar development programs. He has extensive experience in early and late stage drug development across multiple therapeutic areas including immunology, hematology and oncology. He has great passion for innovative approaches to drug development with the aim to improve patient access to medicines.

tim.demuth@sandoz.com

Notes: