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REVIEW

The totality-of-the-evidence approach to the development and assessment of GP2015, a proposed etanercept biosimilar

Vibeke Strand[a], Giampiero Girolomoni[b], Martin Schiestl[c], Robert Ernst Mayer[c], Hilke Friccius-Quecke[d] and Mark McCamish[d]*

[a]Division of Immunology/Rheumatology, Stanford University School of Medicine, Palo Alto, California, USA; [b]Dermatology and Venereology Section, University of Verona School of Medicine, Verona, Italy; [c]Sandoz Biopharmaceuticals, Sandoz International GmbH, Kundl, Austria; [d]Global Biopharmaceutical Development, Sandoz International GmbH, Holzkirchen, Germany

ABSTRACT

Objective: The aim of this review is to describe the inherent variability that is natural to biologics and, using the proposed etanercept biosimilar (GP2015) as an example, provide details on the "totality-of-the-evidence" concept, whereby all physicochemical, biologic, preclinical, and clinical data for a biosimilar and reference medicine are evaluated in an iterative, stepwise manner and shown to be highly similar.

Methods: This review was carried out by a search of published articles, reviews, abstracts and patents in PubMed/Medline and Google Scholar up to November 2016.

Results: Analytical, functional, preclinical, and clinical data provide a comprehensive understanding of both GP2015 and reference etanercept, and demonstrate a high level of similarity between the two products in accordance with regulatory requirements. The totality of the evidence from all analyses and performed trials provides a robust scientific bridge between the biosimilar and clinical experience with the reference medicine, and is used to justify the use of the biosimilar in all indications for which the reference medicine is approved.

Conclusion: Biologic therapies have revolutionized the treatment of immune-mediated inflammatory diseases. The availability of biosimilars has the potential to improve patient access to biologic medicines and stimulate innovation. Physicians may be unfamiliar with the totality-of-the-evidence concept; therefore education and information on this unique approach to developing biosimilars is required to facilitate the use of biosimilars in clinical practice and allow physicians to make informed treatment decisions.

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CONTACT Vibeke Strand vstrand@stanford.ed Division of Immunology/Rheumatology, Stanford University School of Medicine, 306 Ramona Road, Portola Valley CA 94028, USA
*At time of manuscript preparation