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FDA accepts Sandoz regulatory submission for a proposed biosimilar etanercept

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Sandoz, a Novartis company and the global leader in biosimilars, announced today that the US Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA) under the 351 (k) pathway for its proposed biosimilar to Amgen's US-licensed Enbrel (etanercept) - a tumor necrosis factor alpha (TNF-α) inhibitor. Sandoz is seeking approval for all indications included in the label of the reference product which is used to treat a range of autoimmune diseases including rheumatoid arthritis and psoriasis affecting approx. 1.3 million and 7.5 million people (respectively) in the US.

Mark McCamish, M.D., Ph.D., and Head of Global Biopharmaceutical & Oncology Injectables Development at Sandoz said:

> Anti-TNFs will continue to play a leading role in immunology treatment and the acceptance of our regulatory submission by the FDA today is a significant step towards increasing patient access to these life-changing medicines. We believe we are the first company to receive FDA file acceptance of a biosimilar version of etanercept."

This is the second BLA submission by Sandoz using the 351(k) biosimilar pathway. The BLA consists of a comprehensive data package that includes data from analytical, functional, pre-clinical and clinical studies. Sandoz believes that the two pivotal clinical studies; a pharmacokinetic (PK) study in healthy volunteers (HVs) and a confirmatory safety and efficacy study in patients with chronic plaque-type psoriasis (EGALITY), will provide confirmation of similarity to the reference product established in prior analytical comparability investigations.

Sandoz has an unwavering commitment to increasing patient access to high-quality, life-enhancing biosimilars. It is the pioneer and global market leader and currently markets three biosimilars. Sandoz recently launched Zarxio™ (filgrastim-sndz) – the first biosimilar in the United States, signaling a shift toward more competition and affordability in the healthcare system. Sandoz has a leading pipeline with several biosimilars across the various stages of development including five programs in Phase III clinical trials or registration preparation. The company plans to make ten regulatory submissions in the next three years. As part of the Novartis Group, Sandoz is uniquely positioned to lead the biosimilars industry based on its experience and capabilities in development, manufacturing and commercialization.

Source:
Sandoz