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Sandoz receives US FDA approval for biosimilar Hyrimoz

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Hyrimoz is third FDA-approved Sandoz biosimilar in US



Sandoz, a Novartis division and the pioneer and global leader in biosimilars, has announced that the US Food and Drug Administration (FDA) approved its biosimilar, Hyrimoz (adalimumab-adaz). The FDA granted approval for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA) in patients four years of age and older, psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult Crohn's disease (CD), ulcerative colitis (UC) and plaque psoriasis (Ps).

"Biosimilars can help people suffering from chronic, debilitating conditions gain expanded access to important medicines that may change the outcome of their disease," said Stefan Hendriks, Global Head of Biopharmaceuticals, Sandoz. "With the FDA approval of Hyrimoz, Sandoz is one step closer to offering US patients with autoimmune diseases the same critical access already available in Europe."

The FDA approval of Hyrimoz was based on a comprehensive data package comprising analytical, preclinical and clinical research demonstrating that Hyrimoz matches the reference biologic in terms of safety, efficacy and quality. A randomized, double-blind, three-arm, parallel biosimilarity study confirmed the pharmacokinetics, immunogenicity and safety of Hyrimoz. The study met the primary endpoint, demonstrating bioequivalence for all primary pharmacokinetic parameters. A confirmatory efficacy and safety biosimilarity study (ADACCESS) demonstrated therapeutic equivalence in the sensitive indication of patients with moderate to severe chronic plaque-type psoriasis, with a similar safety and immunogenicity profile to the reference biologic.

Rheumatoid arthritis is among the most common types of arthritis and affects approximately 1.3 million adults in the US. Psoriasis is the most prevalent autoimmune disease in the US, and according to recent studies, as many as 7.5 million Americans-approximately 2.2 percent of the population-have psoriasis.

Sandoz is well-positioned to lead the biosimilars industry based on its experience and capabilities in development, manufacturing and commercialization. Hyrimoz is the company's third approved biosimilar medicine in the US. Additional biosimilars for oncology and immunology indications are expected to launch globally across major regions by 2020