

Lupin, Mylan announce positive EMA opinion of Biosimilar Etanercept

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The positive CHMP opinion is based on a biosimilarity assessment which included preclinical and clinical studies



Lupin Limited and Mylan have announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the approval of Nepexto®, a biosimilar to Enbrel® (etanercept), for all indications of the reference product including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis), plaque psoriasis and paediatric plaque psoriasis.

The positive CHMP opinion is based on a biosimilarity assessment which included preclinical and clinical studies demonstrating bioequivalence to the reference product. In addition, a phase 3 clinical study in patients with moderate-to-severe active rheumatoid arthritis confirmed equivalence of Nepexto to the reference product in terms of efficacy, safety and immunogenicity.

The CHMP positive opinion will now be considered by the European Commission (EC). Once approved, the EC will grant a centralized marketing authorization for member countries of the EU. The decision on the EC's approval is expected in May 2020.

Vinita Gupta, CEO, Lupin Limited said, "Biosimilars like Nepexto will play a critical role in expanding access to patients in Europe, providing an effective treatment for multiple therapies including rheumatoid arthritis. We are extremely pleased with the positive CHMP opinion on our application. This milestone brings us one step closer to bringing an affordable biosimilar to etanercept to the European market through our partner Mylan. Once approved by the European Commission, Nepexto will be our first biosimilar to receive regulatory approval in Europe. Building on this progress, we continue to focus on advancing our biosimilar pipeline."

Mylan President, Rajiv Malik commented, "We are pleased with the positive CHMP opinion for Nepexto, biosimilar etanercept. This recommendation validates the strong scientific program supporting this important treatment, which is one of 20 biosimilar products in our broad and diverse biosimilars portfolio, and our shared commitment with Lupin to help increase

access to more affordable biologics treatments, such as etanercept, in Europe and many other regions around the world.” Enbrel had sales of approximately US\$ 9.6 billion globally for the 12 months ending December 2019, according to IQVIA. In June 2018, Lupin and Mylan announced a collaboration to commercialize a biosimilar to etanercept in several global markets.