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The joint venture between Biogen and Samsung BioLogics, Samsung Bioepis, has been granted European Commission (EC) approval for BENEPALI , an etanercept biosimilar referencing Enbrel. BENEPALI has been granted marketing authorization in the European Union (EU) for the treatment of adults with moderate to severe rheumatoid arthritis (RA), psoriatic arthritis, non-radiographic axial spondyloarthritis and plaque psoriasis. Biogen intends to make BENEPALI available for patients in the coming weeks.

BENEPALI is the first etanercept biosimilar referencing Enbrel to be approved in the EU, making it the first subcutaneous anti-TNF biosimilar available there. Anti-TNF's are said to be the largest component of the EU biologics market, accounting for approximately $10 billion of all biologics sold there.

"The approval of BENEPALI is a significant step forward for patients and physicians, and an important milestone for Biogen as we bring to market the first product from our biosimilar pipeline," said Dr Alpna Seth, senior vice president and global head of the biosimilars business unit at Biogen. "As a biotechnology pioneer, Biogen is proud to translate our heritage and expertise in biologics to biosimilars. BENEPALI, as the first etanercept biosimilar referencing Enbrel approved in the EU, can help expand access to treatment options for people affected by chronic inflammatory conditions."

The EC approval was based on a robust preclinical and clinical data package submitted to the European Medicines Agency by Samsung Bioepis. The data in the preclinical submission leveraged sophisticated molecular analytics, technical development and manufacturing expertise. Confirmatory data from well-controlled, head-to-head Phase 1 and Phase 3 clinical trials compared BENEPALI to its reference product Enbrel.

The 52-week, double-blind, Phase 3 study randomized 596 patients with moderate to severe RA despite methotrexate therapy, across more than 70 sites in 10 countries to receive BENEPALI or Enbrel in a 1:1 ratio. Analysis of the primary endpoint showed that BENEPALI had equivalent efficacy to Enbrel, as shown by an ACR20 response at week 24 of 78.1

percent in the BENEPALI arm versus 80.3 percent in the Enbrel arm. Further analysis at 52 weeks confirmed comparable efficacy as shown by an ACR20 response of 80.8 percent in the BENEPALI arm versus 81.5 percent in the Enbrel arm. The safety profile of BENEPALI was comparable to that of Enbrel throughout the study.