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Biocon Biologics secures market entry for Bmab 1200 in Europe, UK, Canada, and Japan

29 August 2024 | News

Biocon Biologics has resolved patent disputes with Janssen to secure market entry dates



Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and a subsidiary of Bengaluru-based Biocon, has signed a settlement and license agreement with Janssen Biotech Inc., Janssen Sciences Ireland, and Johnson & Johnson (collectively known as Janssen) that clears the way to commercialise its Bmab 1200, a proposed biosimilar to Stelara, in Europe, the United Kingdom (UK), Canada, and Japan.

Under the terms of this settlement agreement, Biocon Biologics has resolved patent disputes with Janssen to secure market entry dates in Europe, the UK, Canada, and Japan. Regulatory filings in these markets are currently under review.

Biocon Biologics earlier announced a settlement agreement in the United States for a Bmab 1200 launch no later than February 22, 2025, once approved by the US FDA.

The US FDA has accepted the company's Biologics License Application (BLA) for Bmab 1200 (bUstekinumab) for review under the 351(k) pathway.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd, said, "This settlement agreement is testament to our proven track record of science and innovation and is another key milestone in our journey to bring our biosimilar Bmab 1200 (bUstekinumab) to global markets. Bmab 1200 will significantly strengthen our immunology franchise, enabling us to offer an affordable and effective treatment option for patients impacted by autoimmune diseases."

Stelara (Ustekinumab) is a monoclonal antibody medication that prevents abnormal regulation of interleukin IL-12/23 associated immune diseases and has been approved for the treatment of psoriasis, Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis. The reference brand, Stelara, had worldwide sales of $10.85 billion in 2023.