BioSpectrum the business of Bio & Health Sciences

Biocon Biologics to launch Stelara biosimilar in US in Feb 2025, post FDA approval

29 February 2024 | News

Building further on the company's existing immunology franchise in the US

Bengaluru-based Biocon Biologics has signed a settlement and license agreement with Janssen Biotech Inc., and Johnson & Johnson, that clears the way to commercialise its Bmab 1200, a proposed biosimilar to Stelara, inthe United States of America.

The agreement licenses the company to launch in the United States (US), in February 2025, once approved by the US Food and Drug Administration (FDA).

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

Biocon Biologics and Janssen have finalised the settlement agreement to dismiss the pending*Inter Partes Review* (IPR) for US 10961307 before the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademarks Office.

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 sales of$7 billion in the United States in 2023.

Biocon Biologics has commercialised eight biosimilars in key emerging markets and advanced markets like US, EU,Australia , Canada, Japan.