

PRESS RELEASE

## Biocon Biologics Secures Market Entry for Bmab 1200, a Proposed Biosimilar to Stelara<sup>®</sup>, in Europe, UK, Canada, and Japan

BENGALURU, Karnataka, India: Aug 29, 2024

**Biocon Biologics Ltd (BBL)**, a fully integrated global biosimilars company and a subsidiary of Biocon Ltd (BSE code: 532523, NSE: BIOCON), announced today that the Company 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 commercialize its Bmab 1200, a proposed biosimilar to Stelara<sup>®</sup>, 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 U.S. FDA. The U.S. 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<sup>®</sup> (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<sup>®</sup>, had worldwide sales of \$10.85 billion in 2023<sup>1</sup>.

<sup>1</sup> Johnson & Johnson Reported 2023 Sales

All trademarks, registered or unregistered, are the property of their respective owners.

Product launches in all the countries/ regions are subject to regulatory approval.

### About Biocon Biologics Limited:

**Biocon Biologics Ltd. (BBL)**, a subsidiary of Biocon Limited, is a unique, fully integrated, global biosimilars company committed to transforming healthcare and transforming lives. It is capitalizing on its 'lab to market' capabilities to serve millions of patients across 120+ countries by enabling affordable access to high quality biosimilars. The Company is

leveraging cutting-edge science, innovative tech platforms, global scale manufacturing capabilities and world-class quality systems to lower costs of biological therapeutics while improving healthcare outcomes.

Biocon Biologics has commercialized eight biosimilars in key emerging markets and advanced markets like U.S., Europe, Australia, Canada, and Japan. It has a pipeline of 12 biosimilar assets under development across diabetology, oncology, immunology, ophthalmology, and other non-communicable diseases. The Company has many 'firsts' to its credit in the biosimilars industry. As part of its environmental, social and governance (ESG) commitment, it is advancing the health of patients, people, and the planet to achieve key UN Sustainable Development Goals (SDGs). **Website** [www.bioconbiologics.com](http://www.bioconbiologics.com); Follow us on **X** (formerly Twitter): [@BioconBiologics](https://twitter.com/BioconBiologics) and **LinkedIn**: [Biocon Biologics](https://www.linkedin.com/company/biocon-biologics) for company updates.

**Biocon Limited**, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as Generic Formulations in the US, Europe & key emerging markets. It also has a pipeline of promising novel assets in immunotherapy under development.

**Website:** [www.biocon.com](http://www.biocon.com); Follow-us on **X** (formerly Twitter) [@bioconlimited](https://twitter.com/bioconlimited) and **LinkedIn**: [Biocon](https://www.linkedin.com/company/biocon) for company updates.

### Forward-Looking Statements: Biocon

*This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.*

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