

PRESS RELEASE

## Biocon Biologics Secures US Market Entry Date for Bmab 1200, a Proposed Biosimilar to Stelara®

**BRIDGEWATER, N.J., United States and BENGALURU, Karnataka, India: February 29, 2024**

**Biocon Biologics Ltd (BBL)**, a fully integrated global biosimilars company and 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., and Johnson & Johnson (collectively known as Janssen) that clears the way to commercialize its Bmab 1200, a proposed biosimilar to Stelara®, in the United States of America.

The agreement licenses the Company to launch in the United States, in February 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.

Biocon Biologics and Janssen have finalized 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.

*Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd, said: "This settlement agreement reflects our commitment and focus on science and innovation. We are pleased that this allows Biocon Biologics to be amongst the first launch group to offer a reliable, high quality biosimilar option to patients and healthcare providers in the United States with our bUstekinumab, Bmab 1200. This development enables Biocon Biologics to build further on our existing immunology franchise in the US. As a fully integrated biosimilars company, Biocon Biologics is committed to expanding access to life-changing treatments with our broad portfolio of products."*

*Matthew Erick, Chief Commercial Officer – Advanced Markets, Biocon Biologics Ltd, said: "This agreement for a biosimilar Ustekinumab is an important milestone in our company's commitment to delivering affordable, life-changing biosimilar medicines. It underscores the Company's steadfast resolution of supporting the well-being of patients impacted by inflammatory diseases and driving positive change within the healthcare industry."*

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<sup>1</sup>.

<sup>1</sup>Company Reported 2023 Sales. All trademarks, registered or unregistered, are the property of their respective owners.

**About Biocon Biologics Limited: Biocon Biologics Ltd. (BBL)**, a subsidiary of Biocon Ltd., is a unique, fully integrated, global biosimilars company committed to transforming healthcare and transforming lives by

enabling affordable access to high quality biosimilars for millions of patients worldwide. It 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.

BBL has acquired the global biosimilars business of its long-standing partner Viartis, which is a historic milestone in its value creation journey. Biocon Biologics has commercialized eight biosimilars in key emerging markets and advanced markets like U.S., EU, Australia, Canada, Japan.

The Company has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology, and other non-communicable diseases. It has many 'firsts' to its credit in the biosimilars industry. As part of its environmental, social and governance (ESG) commitment, BBL 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 Twitter: @BioconBiologics 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 Twitter: @bioconlimited 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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