Press Release

Biocon Biologics Announces New Dermatology Data to Be Presented at EADV Congress 2024

- Switching between adalimumab and adalimumab-fkjp in Phase 3 study in patients with chronic plaque psoriasis supports interchangeability between adalimumab and adalimumab-fkjp
- Biosimilarity between Bmab 1200 and reference biologic-Ustekinumab in pivotal Phase 3 trial in patients with moderate to severe chronic plaque psoriasis

AMSTERDAM, Netherlands, and ***BENGALURU, Karnataka, India***, ***September 25, 2024***

Biocon Biologics Ltd (BBL), a subsidiary of Biocon Ltd (BSE code: 532523, NSE: BIOCON), today announced new dermatology data presented at the European Academy of Dermatology and Venereology (EADV) 2024 Congress in Amsterdam. The results from two separate pivotal Phase 3 clinical studies supported interchangeability between adalimumab and adalimumab-fkjp as well as underscoring biosimilarity of bUstekinumab.

Uwe Gudat, M.D., Chief Medical Officer, Biocon Biologics said, "The extensive range of new data being presented at EADV this year underscores Biocon Biologics' commitment to a high-science portfolio of biosimilar medicines that meet the clinical needs of physicians and patients while providing important sustainability benefits to health systems. These clinical studies support the interchangeability of adalimumab-fkjp at low-concentration with high-concentration adalimumab and ustekinumab biosimilarity without variation of clinical outputs in patients with chronic plaque psoriasis."

Poster Title: Multiple switching between the biosimilar adalimumab-fkjp low concentration and reference adalimumab high concentration in patients with chronic plaque psoriasis: a phase 3, double-blind, randomised, parallel-group study
Authors: Sarika Deodhar, Subramanian Loganathan, Ramesh Ks, Gopi Ranganna, Shiyao Liu, Matthew A. Hummel Hummel, Stefan Daniluk, Anna Hanczewska, Kamelia Vekovska, Maria Zegadlo-Mylik, Grazyna Pulka, Elena Wolff-Holz
Abstract ID: 3809
Poster ID: P3241
Date/Time: 9:00am EDT, September 25, 2024

This study evaluated the pharmacokinetics (PK), efficacy, safety, and immunogenicity in patients with moderate to severe chronic Plaque Psoriasis (PPs) receiving adalimumab continuously and those undergoing repeated switches between reference adalimumab and adalimumab-fkjp. The primary objective was to evaluate interchangeability of low-concentration adalimumab-fkjp (40 mg/0.8ml) and high-concentration adalimumab (40 mg/0.4ml) by comparing adalimumab steady-state PK between switching and non-switching arms.

The overall number and proportion of patients with Psoriasis Area and Severity Index (PASI) responses and static Physicians Global Assessment (sPGA) success were highly similar between the two arms at week 28. Treatment-emergent Adverse Events were comparable between switching [54 subjects (29.8%)] and non-switching arms [66 subjects (34.2%)]. The overall number and proportion of patients with PASI responses and sPGA success were highly similar between the two arms at week 28.

This study confirmed that the subjects receiving adalimumab-fkjp low concentration and adalimumab high concentration in alternate fashion had highly similar time concentration curves compared to continuous administration of high-concentration reference adalimumab, and demonstrated PK equivalence between switching and non-switching arms. The overall data supports interchangeability between high-concentration adalimumab and low-concentration adalimumab-fkjp.

This study was conducted to fulfill the U.S. Food and Drug Administration (FDA) requirement for designation as an "interchangeable" and has been submitted to the FDA.

Uwe Gudat, M.D., Chief Medical Officer, Biocon Biologics said, "For physicians, an important unmet need is understanding the comparative safety, efficacy and exposure of an adalimumab biosimilar formulated at a low concentration and high-concentration adalimumab at dose parity. The data from the study shows clearly that in patients the same safety, efficacy and exposure when used at dose parity can be expected for both products. This in the context of multiple switches between the reference product and the biosimilar as required of an interchangeability study."

Poster Title: A Randomized, Double-blind, Parallel Group, Multicenter, Phase 3 Study to Compare the Efficacy and Safety of Bmab 1200 and Reference Biologic-Ustekinumab in Patients with Moderate to Severe Chronic Plaque Psoriasis 28-week Results
Authors: Jacek Szepietowski, Adam Reich, Steven Feldman, Grazyna Pulka, Lally Mekokishvili, Nino Junior Tsiskarishvili, Inese Kolontaja-Zaube, Airi Poder, Gursharan Singh, Subramanian Loganathan, Elena Wolff-Holz, Sarika Deodhar, Ashwani Marwah, Sandeep Athalye
Abstract ID: 4382
Poster ID: P3266
Date/Time: 9:00am EDT, September 25, 2024

This pivotal Phase 3, randomized, double-blind, active controlled, parallel-group, multicenter study compared the efficacy, safety, immunogenicity, and pharmacokinetics (PK) of Bmab 1200 with the reference product ustekinumab in adult patients with moderate to severe chronic plaque psoriasis (Pso).

A total of 384 patients were evaluated for 52 weeks and the primary efficacy endpoint was percentage change from baseline (%CFB) in PASI at Week 12. In the primary efficacy analysis at 28 weeks, Bmab 1200 and ustekinumab were equivalent and the data support biosimilarity. The

study established equivalent efficacy and comparable safety of Bmab 1200 with ustekinumab in patients with moderate to severe chronic plaque Pso.

Uwe Gudat, M.D., Chief Medical Officer, Biocon Biologics said, "This pivotal trial of bUstekinumab clearly met the safety and efficacy endpoints, thereby fulfilling the expectations set for a biosimilar. bUstekinumab offers tangible promise for all patients qualifying for treatment with Ustekinumab."

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; Follow us on **X** *(formerly Twitter)*: @BioconBiologics and **LinkedIn**: 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.

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