Biocon Limited
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CIN : L24234KA1978PLC003417

www.biocon.com

BIO/SECL/TG/2025-26/16

April 26, 2025

To The Manager, **BSE Limited** Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001	To The Manager, **National Stock Exchange of India Limited** Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050
Scrip Code - 532523	**Scrip Symbol - BIOCON**

Subject: Company Statement

Dear Sir/Madam,

Please find enclosed Company Statement w.r.t. **"Biocon Biologics Receives Positive CHMP Opinions for Biosimilar Denosumab in Europe".**

The above information will also be available on the website of the Company at www.biocon.com.

Kindly take the same on record and acknowledge.

Thanking You,

Yours faithfully,

For **Biocon Limited**

SIDDHARTH MITTAL
Digitally signed by SIDDHARTH MITTAL
Date: 2025.04.26 11:09:46 +05'30'

Siddharth Mittal
Managing Director & CEO
DIN: 03230757

Encl: Company Statement

Notification To Stock Exchange

COMPANY STATEMENT

Biocon Biologics Receives Positive CHMP Opinions for Biosimilar Denosumab in Europe

Bengaluru, Karnataka, India, April 26, 2025

Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd (BSE code: 532523, NSE: BIOCON), today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has issued positive opinions recommending the approval of its denosumab biosimilars candidates for distinct therapeutic indications for bone health: *Vevzuo®* and *Denosumab BBL* (brand name is currently under approval).

The positive opinions are based on applications submitted by Biosimilar Collaborations Ireland Limited, an indirect wholly owned subsidiary of Biocon Biologics Ltd.

These recommendations follow a review of comprehensive data packages, including clinical studies results[1], which demonstrated comparability with the reference product in terms of pharmacokinetic, safety, efficacy and immunogenicity profiles.

The European Commission will review the CHMP opinions and, following its decision, detailed information on the approved indications and usage will be included into the Summary of Product Characteristics (SmPCs), and the European Public Assessment Reports (EPARs), available in all official European Union languages.

Until marketing authorisations are granted by the European Commission, these products are not approved for use in the European Union.

– Company Spokesperson

[1] Anna Strzelecka, Grzegorz Kania, Pawan Kumar Singh, Kuldeep Kumar, Binay Kumar Thakur, Ashwani Marwah, Sudipta Basu, Nitin Madhukar Chaudhari, Sarika S Deodhar, Elena Wolff-Holz, Sandeep Nilkanth Athalye, Subramanian Loganathan. A Randomized, Double-blind, Multicenter, Parallel-arm Phase 3 Study to Compare the Efficacy, Pharmacodynamics, Safety, and Immunogenicity between Bmab-1000 and Prolia in Postmenopausal Women with Osteoporosis. Poster presented at ACR Congress 2024

R. Eastell, E. Orwoll, F. Cosman, A. Strzelecka, G. Kania, R. Plebanski, A. Mansukhbhai Ranpura, K. Kumar, B. Kumar Thakur, A. Marwah, S. Basu, N. Madhukar Chaudhari, S. S Deodhar, E. Wolff-Holz, S. Loganathan. Equivalence Trial of Proposed Denosumab Biosimilar Bmab-1000 And Reference Denosumab In Postmenopausal Osteoporosis: The Devote Study. Poster presented at WCO-IEF-ESCEO 2025