



Biocon Limited
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CIN : L24234KA1978PLC003417

www.biocon.com

BIO/SECL/SG/2024-25/141

December 15, 2024

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

Subject: Notification to Stock Exchanges

Please find enclosed the company statement titled “**EMA’s CHMP recommends approval of Biocon Biologics’ YESINTEK®, biosimilar to J&J’s Stelara®**”.

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**

Mayank Verma
Company Secretary & Compliance Officer
Membership No: ACS 18776

Encl: as above

NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

EMA's CHMP recommends approval of Biocon Biologics' YESINTEK[®], biosimilar to J&J's Stelara[®]

Bengaluru, Karnataka, India, December 15, 2024

Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd (BSE code: 532523, NSE: BIOCON), today announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued **a positive opinion recommending approval of YESINTEK[®], an Ustekinumab biosimilar** intended for the treatment of adults and children with plaque psoriasis and adults with psoriatic arthritis or Crohn's disease - based on the application filed by Biosimilar Collaborations Ireland Limited, an indirect wholly owned subsidiary of BBL.

Clinical studies showed that the Ustekinumab biosimilar has a similar pharmacokinetic, safety, efficacy and immunogenicity profile compared with the originator product.

Detailed recommendations for the use of YESINTEK[®] will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP positive opinion follows [recent approval by the U.S. FDA](#) earlier this month.

– *Company Spokesperson*

For more information: seema.ahuja@biocon.com