

Biocon Biologics Limited

CIN: U24119KA2016PLC093936

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December 15, 2024

Singapore Exchange Securities Trading Limited

4 Shenton Way # 02-01

SGX Centre 2 Singapore 068807

Dear Sir/Madam,

Subject: Company Statement

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

Kindly take the same on record and acknowledge.

Thanking you

Your faithfully

For Biocon Biologics Limited

Akhilesh
Nand

Digitally signed by
Akhilesh Nand
Date: 2024.12.15
16:12:29 +05'30'

Akhilesh Nand

Company Secretary

Membership No. ACS 13669

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