

January 31, 2025

To

Listing Department,

NATIONAL STOCK EXCHANGE OF INDIA LIMITED

Exchange Plaza,

Bandra Kurla Complex, Bandra (E),

MUMBAI -400 051

Company Code No. AUROPHARMA

To

The Corporate Relations Department

BSE LIMITED

Phiroz Jeejeebhoy Towers, 25th floor, Dalal Street, **MUMBAI -400 001**

Company Code No. 524804

Dear Sir/ Madam,

Sub: Press Release - CuraTeQ Biologics s.r.o, receives positive opinion from CHMP / EMA for Dyrupeg

We enclose a copy of the Press Release that is being issued by the Company informing that the Committee for Medicinal Products for Human Use (CHMP) within the European Medicines Agency (EMA) has adopted a positive opinion for Dyrupeg (BP14, a pegylated filgrastim biosimilar) recommending the granting of marketing authorization to CuraTeQ Biologics s.r.o, a step-down wholly owned subsidiary of the Company.

Please take the information on record.

Thanking you,

Yours faithfully,
For AUROBINDO PHARMA LIMITED

B. Adi Reddy Company Secretary

Encl.: Press Release

(CIN: L24239TG1986PLC015190)

AUROBINDO PHARMA LIMITED



Hyderabad, India, January 31, 2025

CuraTeQ Biologics receives positive opinion for biosimilar Dyrupeg™ from EMA

CuraTeQ Biologics s.r.o., a step-down subsidiary of Aurobindo Pharma Limited, is pleased to announce that the Committee for Medicinal Products for Human Use (CHMP) within the European Medicines Agency (EMA) has adopted a positive opinion for Dyrupeg[™] (BP14, a pegylated filgrastim biosimilar) recommending the granting of a marketing authorisation. The CHMP positive opinion is expected to translate into a formal decision of approval by the European Commission in April 2025.

Dyrupeg™ will be available as 6 mg solution for injection in prefilled syringe and is intended for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

Commenting on the update, Dr. Satakarni Makkapati, Director Aurobindo Pharma and CEO Biologics, Vaccines and Peptides said "After receiving the GMP certificate of compliance from the EMA in November, the positive opinion of Dyrupeg™ from CHMP follows the marketing approval of Bevqolva™ (a bevacizumab biosimilar) by UK's MHRA in December 2024, and CHMP's positive opinion of Zefylti™ (a filgrastim biosimilar) in December 2024. The CHMP positive opinion of Dyrupeg™ is based upon a review of evidence of analytical biosimilarity, demonstrating equivalence and no clinically meaningful differences in pharmacokinetics, pharmacodynamics, and immunogenicity to the EU-registered reference product Neulasta™. We intend to bring these treatment options to patients in Europe in the second half of 2025 and are on course to file in additional markets for approval."

Aurobindo Pharma's Vice Chairman and Managing Director Mr. K. Nithyananda Reddy said, "The positive opinion received from CHMP for Dyrupeg™ furthers our commitment in developing high quality biosimilars and driving access to patients suffering from illnesses such as cancer. CuraTeQ has a broad pipeline of biosimilars across oncology and immunology segments and we are enthusiastic about the prospect of adding these over time to Aurobindo's commercial portfolio in global markets."

About CuraTeQ Biologics Private Limited

CuraTeQ Biologics Private Limited (CuraTeQ), a subsidiary of Aurobindo Pharma Limited, is a global biopharmaceutical company headquartered in Hyderabad, India. CuraTeQ's vision is to improve the wellbeing of patients suffering from debilitating illnesses by providing them access to high quality and cost-effective biosimilars. It is focused on developing biosimilars for the treatment of various cancers and autoimmune diseases. CuraTeQ's pipeline consists of fourteen biosimilars, primarily targeting the immunology and oncology segments. It has end-to-end capabilities in producing a full range of products from bulk drug substance to fill-finish and packaged drug products.

AUROBINDO PHARMA LIMITED

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www.aurobindo.com



About Aurobindo Pharma Limited

Aurobindo Pharma Limited (www.aurobindo.com), (NSE: AUROPHARMA, BSE: 524804, Reuters: ARBN.NS, Bloomberg: ARBP IN) is an integrated global pharmaceutical company headquartered in Hyderabad, India. The Company develops, manufactures, and commercializes a wide range of generic pharmaceuticals, branded specialty pharmaceuticals and active pharmaceutical ingredients globally in over 150 countries.

The company has 29 manufacturing and packaging facilities that are approved by leading regulatory agencies including USFDA, UK MHRA, EDQM, Japan PMDA, WHO, Health Canada, South Africa MCC, Brazil ANVISA. The Company's robust product portfolio is spread over seven major therapeutic/product areas encompassing CNS, Anti-Retroviral, CVS, Antibiotics, Gastroenterological, Anti-Diabetics and Anti-Allergic, supported by a strong R&D set-up.

To know more, please log on to <u>www.aurobindo.com</u> For further information or queries, please contact:

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Disclaimer:

This press release contains statements that may constitute "forward looking statements" including and without limitation, statements relating to product characteristics and uses, sales potential and target dates for product launch, implementation of strategic initiatives, and other statements relating to our future business developments and economic performance. While these forward-looking statements represent our judgment and future expectations concerning the development of our business, a number of risks, uncertainties and other factors could cause actual developments and results to differ materially from our expectations. The company undertakes no obligation to publicly revise any forward-looking statements to reflect future events or circumstances and will not be held liable for any use of this information.

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