July 4, 2023

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 announces positive result in phase 3 clinical trial for its proposed Trastuzumab Biosimilar product.

We enclose a copy of the Press Release that is being issued by the Company in connection with announcement by CuraTeQ Biologics Private Limited, a wholly owned subsidiary of the Company, on positive result in phase 3 clinical trial for its proposed Trastuzumab Biosimilar product.

Please take the information on record.

Thanking you,

Yours faithfully,
For **AUROBINDO PHARMA LIMITED**

ADIREDDY BADDIGAM
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B. Adi Reddy
Company Secretary

Encl: as above

Hyderabad, India, 4th July 2023

CuraTeQ Biologics announces positive result in phase 3 clinical trial for its proposed Trastuzumab Biosimilar product

Aurobindo Pharma Limited (along with its subsidiaries together referred to as "Aurobindo") is pleased to announce that the breast cancer biosimilar product, BP02 (Trastuzumab or biosimilar to Herceptin), developed by its wholly owned subsidiary company, Curateq Biologics Private Limited, has met its primary endpoint in Phase 3 clinical trial (Trial No.: CR201-18). BP02 has shown equivalent efficacy to Herceptin® in regard to its clinical response (overall response rate, ORR), in addition to demonstrating a comparable safety profile.

This phase 3 study is a multi-centre, randomized, double-blinded study involving females with metastatic HER2-positive breast cancer. The trial was carried out to demonstrate product equivalence in terms of efficacy vis-à-vis EU sourced Herceptin®. Additionally, the trial also compared pharmacokinetics, safety, and immunogenicity of BP02 vs originators product. The trial enrolled a total of 690 patients, who were randomly assigned in a 1:1 ratio to one of the two parallel treatment groups. They received concomitant chemotherapy (docetaxel). The overall response rate fell well within both the FDA risk ratio-based equivalency margin (0.80 - 1.25) and the EMA risk difference-based equivalency margin (-13, +13). The results demonstrated that BP02 met equivalence to Herceptin® in terms of clinical response and the safety profiles of the two treatment arms were shown to be comparable during the treatment phase.

Earlier, CuraTeQ completed a randomized, double-blind, parallel three arm Phase 1 study (BP02-101) in healthy volunteers with BP02 and Herceptin® sourced from the US and EU. The study included 111 healthy volunteers who were administered a single dose of BP02 or EU-Herceptin® or US-Herceptin® in a 1:1:1 ratio. The results demonstrated similar bioavailability (point estimate of 1.0) and all the pharmacokinetic parameters were within the equivalency margin of 0.80 -1.25. BP02 was proven to be bioequivalent to Herceptin® sourced from the US and EU.

Dr.Satakarni Makkapati, CEO, Biosimilars, Vaccines and Peptides said, "We are excited by this study outcome. CuraTeQ is in the process of initiating submissions to regulatory agencies starting this quarter. We hope to complete market authorization (MA) application submissions across all key regulated markets in a phased manner, by March 2024. Our first submission will be in India in July 2023.".

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 24 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 7 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 www.aurobindo.com

For further information or queries, please contact:

Soumen Biswas | Deepti Thakur
Investor Relations | Corporate Communications
Phone: +91 40 66725401 / 66725000
Email: ir@aurobindo.com

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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