

April 12, 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 - Aurobindo Pharma receives final ANDA approval for Rivaroxaban Tablets USP, 2.5mg and tentative approval for other strengths of Rivaroxaban Tablets USP

We enclose a copy of the Press Release that is being issued by the Company in connection with receipt of final ANDA approval for Rivaroxaban Tablets USP, 2.5mg and tentative approval for other strengths of Rivaroxaban Tablets USP

Please take the information on record.

Thanking you,

Yours faithfully,
For AUROBINDO PHARMA LIMITED

B. Adi Reddy Company Secretary\

Encl: as above

### **AUROBINDO PHARMA LIMITED**

(CIN: L24239TG1986PLC015190)

www.aurobindo.com

Corp. Off.: Galaxy, Floors: 22-24, Plot No.1, Survey No.83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad – 500 032, Telangana, India. Tel: +91 40 6672 5000 / 6672 1200 Fax: +91 40 6707 4044.



#### Hyderabad, India, April 12, 2025

Aurobindo Pharma receives final ANDA approval for Rivaroxaban Tablets USP, 2.5mg and tentative approval for other strengths of Rivaroxaban Tablets USP

Aurobindo Pharma Limited (Aurobindo Pharma) is pleased to announce that it has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Rivaroxaban Tablets USP, 2.5 mg, which is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), XARELTO®, 2.5 mg of Janssen Pharmaceuticals Inc. The product will be launched in Q1FY26.

The approved product, Rivaroxaban Tablets USP, 2.5mg, has an estimated US market size of US\$ 447 million for the twelve months ending February 2025, according to IQVIA. Aurobindo Pharma now has a total of 540 ANDA approvals (521 Final approvals and 19 tentative approvals) from USFDA.

Rivaroxaban Tablet USP is used (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

Aurobindo Pharma also received tentative approval from USFDA for 10 mg, 15 mg, and 20 mg strengths of Rivaroxaban Tablets USP. The estimated market size of all the strengths of Rivaroxaban tablets USP, in the US, is US\$ 8.5 billion for the twelve months ending February 2025, according to IQVIA.

### **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 30 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 www.aurobindo.com

For further information or queries, please contact:

Investor Relations Corporate Communications

Phone: +91 40 66721551 / 66725000 Phone: +91 40 66725005 / 66725000

Email: ir@aurobindo.com Email: ccommunications@aurobindo.com

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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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