

December 27, 2023

Τo

Listing Department,

NATIONAL STOCK EXCHANGE OF INDIA LIMITED

Exchange Plaza,

Bandra Kurla Complex, Bandra (E),

MUMBAI -400 051

Company Code No. AUROPHARMA

Tο

The Corporate Relations Department

**BSE LIMITED** 

Phiroz Jeejeebhoy Towers, 25<sup>th</sup> floor, Dalal Street,

MUMBAI -400 001

Company Code No. 524804

Dear Sir/ Madam,

Sub: Press Release - Eugia Pharma receives USFDA Approval for Posaconazole Injection, 300 mg/16.7 mL (18 mg/mL), Single-Dose Vial.

We enclose a copy of the Press Release that is being issued by the Company in connection with USFDA approval received by Eugia Pharma Specialities Limited, a wholly owned subsidiary of the Company, for Posaconazole Injection, 300 mg/16.7 mL (18 mg/mL), Single-Dose Vial.

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

PAN No. AABCA7366H

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Tel: +91 40 6672 5000 / 6672 1200 Fax: +91 40 6707 4044.



## Hyderabad, India, December 27, 2023

Eugia Pharma receives USFDA Approval for Posaconazole Injection, 300 mg/16.7 mL (18 mg/mL), Single-Dose Vial

Aurobindo Pharma Limited is pleased to announce that its wholly owned subsidiary company, Eugia Pharma Specialities Limited, has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Posaconazole Injection, 300 mg/16.7 mL (18 mg/mL), Single-Dose Vial, which is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Noxafil Injection, 300 mg/16.7 mL (18 mg/mL), of Merck Sharp & Dohme LLC (Merck). The product is expected to be launched in December 2023. The approved product has an estimated market size of US\$ 25.4 million for the twelve months ending October 2023, according to IQVIA.

This is the 173<sup>rd</sup> ANDA approval (including 8 tentative approvals received) out of Eugia Pharma Specialities Group (EPSG) facilities, manufacturing both oral and sterile specialty products.

Posaconazole Injection, 300 mg/16.7 mL (18 mg/mL), Single-Dose Vial is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

## **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 25 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:

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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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