

May 26, 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 Carboprost Tromethamine Injection USP 250 mcg/mL

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 Carboprost Tromethamine Injection USP 250 mcg/mL.

Please take the information on record.

Thanking you,

Yours faithfully,
For AUROBINDO PHARMA LIMITED

B. Adi Reddy Company Secretary

Encl: as above

(CIN: L24239TG1986PLC015190)

**AUROBINDO PHARMA LIMITED** 

www.aurobindo.com

PAN No. AABCA7366H

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, May 26, 2023

### Eugia Pharma receives USFDA Approval for Carboprost Tromethamine Injection USP 250 mcg/mL.

Aurobindo Pharma Limited is pleased to announce that its wholly owned subsidiary company, Eugia Pharma Specialties Limited, has received a final approval from the US Food & Drug Administration (USFDA) to manufacture and market Carboprost Tromethamine Injection USP 250 mcg/mL, Single-Dose Vials, which is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Hemabate Injection, 250mcg/mL, of Pfizer Inc. The product is expected to be launched in June 2023. The approved product has an estimated market size of around US\$51.4 million for the twelve months ending March 2023, according to IQVIA.

This is the 159<sup>th</sup> approved ANDA (including 8 tentative approvals received) out of Eugia Pharma Specialty Group (EPSG) facilities, manufacturing both oral and sterile specialty products.

- It is indicated for aborting pregnancy between the 13th and 20th weeks of gestation as calculated from the first day of the last normal menstrual period and in the following conditions related to second trimester abortion:
- Failure of expulsion of the fetus during the course of treatment by another method.
- Premature rupture of membranes in intrauterine methods with loss of drug and insufficient or absent uterine activity.
- Requirement of a repeat intrauterine instillation of drug for expulsion of the fetus.
- Inadvertent or spontaneous rupture of membranes in the presence of a previable fetus and absence of adequate activity for expulsion.

Carboprost Tromethamine injection is indicated for the treatment of postpartum hemorrhage due to uterine atony which has not responded to conventional methods of management. Prior treatment should include the use of intravenously administered oxytocin, manipulative techniques such as uterine massage and, unless contraindicated, intramuscular ergot preparations. Studies have shown that in such cases, the use of Carboprost Tromethamine injection has resulted in satisfactory control of hemorrhage, although it is unclear whether or not ongoing or delayed effects of previously administered ecbolic agents have contributed to the outcome. In a high proportion of cases, Carboprost Tromethamine injection used in this manner has resulted in the cessation of lifethreatening bleeding and the avoidance of emergency surgical intervention.

## **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.

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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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