

**NEWS RELEASE**

31<sup>st</sup> January 2020, Hyderabad, India

**Eugia Pharma receives USFDA Approval for Methotrexate Tablets**

Aurobindo Pharma Limited is pleased to announce that its joint venture company, Eugia Pharma Specialities Limited, has received a final approval from the US Food & Drug Administration (USFDA) to manufacture and market Methotrexate tablets, 2.5 mg. Methotrexate tablets are generic version of Dava Pharmaceuticals' Rheumatrex Tablets. The product will be launched in March 2020. The approved product has an estimated market size of US\$ 98 million for the twelve months ending December 2019, according to IQVIA.

This is the 9<sup>th</sup> ANDA (including 1 tentative approval) to be approved out of Eugia formulation facility in Hyderabad, India, a manufacturing facility for oral and injectable products. Aurobindo now has a total of 420 ANDA approvals (393 Final approvals including 22 from Aurolife Pharma LLC and 27 tentative approvals) from USFDA.

Methotrexate tablets are indicated in the treatment of

- Gestational choriocarcinoma, chorio-adenoma destruens and hydatidiform mole
- Used alone or in combination with other anticancer agents in the treatment of breast cancer, epidermoid cancers of the head and neck, advanced mycosis fungoides (cutaneous T cell lymphoma), and lung cancer, particularly squamous cell and small cell types
- Symptomatic control of severe, recalcitrant, disabling psoriasis.
- Selected adults with severe, active, rheumatoid arthritis (ACR criteria), or children with active polyarticular-course juvenile rheumatoid arthritis.

**About Aurobindo Pharma Limited:**

Aurobindo Pharma Limited ([www.aurobindo.com](http://www.aurobindo.com)) (NSE: AUROPHARMA, BSE: 524804, Reuters: ARBN.NS, Bloomberg: ARBP:IN), headquartered at Hyderabad, India, manufactures generic pharmaceuticals and active pharmaceutical ingredients. The company's manufacturing facilities are approved by several leading regulatory agencies like US FDA, UK MHRA, Japan PMDA, WHO, Health Canada, MCC South Africa, ANVISA Brazil. The company's robust product portfolio is spread over major therapeutic/product areas encompassing Antibiotics, Anti-Retrovirals, CVS, CNS, Gastroenterologicals, Anti-Allergies and Anti-Diabetics, supported by an outstanding R&D set-up. The Company is marketing these products globally, in over 150 countries.

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