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Aurobindo Pharma receives USFDA Approval for Azithromycin for Injection

Aurobindo Pharma Limited is pleased to announce that the company has received final approvals from the US Food & Drug Administration (USFDA) to manufacture and market Azithromycin for Injection USP, 500mg /vial (ANDA 203294).

Azithromycin for Injection USP, 500mg /vial is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) Zithromax® (Azithromycin for Injection) 500mg/vial of Pfizer, Inc. Azithromycin for injection, USP is a macrolide antibacterial drug indicated for the treatment of patients with infections caused by susceptible strains of the designated microorganisms in the conditions such as Community-Acquired Pneumonia and Pelvic Inflammatory Disease

Aurobindo now has 12 ANDAs (represented by 9 product classes) approved out of Unit IV formulation facility in Hyderabad, India for manufacturing general injectable products and will be marketed and sold by Aurobindo's wholly owned subsidiary AuroMedics Pharma LLC

About Aurobindo Pharma Limited:

Aurobindo Pharma Limited (www.aurobindo.com), 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 6 major therapeutic/product areas encompassing Antibiotics, Anti-Retrovirals, CVS, CNS, Gastroenterologicals, and Anti-Allergics, supported by an outstanding R&D set-up. The Company is marketing these products globally, in over 125 countries.

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