Press Release *For Immediate Release*

Granules India Limited Receives ANDA Approval for Glycopyrrolate Oral Solution

Hyderabad, 20 August 2024: Granules India announced today that the U.S. Food and Drug Administration (FDA) has approved its Abbreviated New Drug Application (ANDA) for Glycopyrrolate Oral Solution 1mg/5mL filed by Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the Company.

It is bioequivalent and therapeutically equivalent to the reference listed drug, Cuvposa Oral Solution, 1 mg/5 mL of Merz Pharmaceuticals, LLC.

Glycopyrrolate Oral Solution is an anticholinergic medication indicated for pediatric patients aged three to 16 years who have neurological conditions associated with problem drooling.

"As we strengthen Granules' footprint in the U.S. market, this approval highlights our robust quality systems, ensuring compliance with the highest regulatory standards," said Dr. Krishna Prasad Chigurupati, Chairman and Managing Director, Granules India Limited.

About Granules India Ltd. (BSE: 532482, NSE: GRANULES)

Granules India Limited, incorporated in 1991 is a vertically integrated fast-growing Indian pharmaceutical company headquartered in Hyderabad with best-in-class facilities and a commitment to operational excellence, quality, and customer service. We are among the few pharmaceutical companies in the world to be present in the manufacturing of the entire value chain – from Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs), and Finished Dosages (FDs). Our products are being distributed to over 300+ customers in regulated and semi-regulated markets with a global presence extending to over 80+ countries with offices across India, U.S., and U.K. The Company has 10 manufacturing facilities out of which 8 are located in India and 2 in USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.

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