Press Release *For Immediate Release*

Granules India Limited Announces FDA Approval for ADHD Treatment, Addressing Drug Shortages in the U.S.

Hyderabad, December 17, 2024 – Granules India Limited, a vertically integrated Indian pharmaceutical company, announced today that its wholly-owned foreign subsidiary, Granules Pharmaceuticals, Inc. (GPI), has received approval from the U.S. Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Lisdexamfetamine Dimesylate Chewable Tablets. The approved drug is available in multiple strengths: 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg.

This generic drug product has been determined to be bioequivalent (AB Rating) to the reference listed drug, Vyvanse® Chewable Tablets by Takeda Pharmaceuticals USA Inc. Lisdexamfetamine dimesylate chewable tablets are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients aged six years and older, as well as Moderate to Severe Binge Eating Disorder (BED**)** in adults.

Granules has received approval in the first review cycle, reflecting the company's consistent focus on regulatory excellence and expedited product delivery. Lisdexamfetamine Dimesylate Chewable Tablets are currently published on the FDA Drug Shortages List, emphasizing their critical role in patient care.

Commenting on the approval, Dr Krishna Prasad Chigurupati, Chairman & Managing Director of Granules Limited, said, "This milestone reflects our unwavering commitment to addressing unmet patient needs by delivering high-quality, affordable medications. With this approval, GPI reinforces its dedication to alleviating critical drug shortages in the U.S. healthcare market."

Granules India Limited now holds 68 ANDA approvals, including 30 ANDAs from GPI.

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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