Press Release

Granules Strengthens ADHD Portfolio with FDA Approval for Lisdexamfetamine Dimesylate Capsules

Hyderabad, 30 January 2025 – Granules India Limited, a vertically integrated Indian pharmaceutical company, announced today that its wholly-owned foreign subsidiary, Granules Pharmaceuticals, Inc. (GPI), has received final approval from the U.S. Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Lisdexamfetamine Dimesylate Capsules in strengths of 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg.

This generic drug product is bioequivalent and therapeutically equivalent to the reference listed drug, Vyvanse® Capsules, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg, of Takeda Pharmaceuticals U.S.A., Inc. Lisdexamfetamine Dimesylate is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients aged six years and older, as well as for Moderate to Severe Binge Eating Disorder (BED) in adults.

This approval follows the company's recent December 2024 USFDA approval for Lisdexamfetamine Dimesylate Chewable Tablets, further expanding Granules' comprehensive portfolio in the ADHD therapeutic segment and demonstrating the company's commitment to providing multiple treatment options for patients.

With this latest approval, Granules India Limited now holds a total of 69 ANDA approvals, with 38 secured under the name of Granules India Limited (GIL) and 31 under Granules Pharmaceuticals, Inc. (GPI).

Dr. Krishna Prasad Chigurupati, Chairman & Managing Director of Granules India Limited, said **"**With this latest approval, we are reinforcing our presence in the ADHD treatment space and strengthening our portfolio of complex generics."

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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