



REGISTERED OFFICE

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CIN: L24110TG1991PLC012471

Date: December 17, 2024

To,
National Stock Exchange of India Limited
BSE Limited
Symbol: NSE: GRANULES: BSE: 532482

Sub: Press Release

Dear Sir,

We are herewith enclosing the press release given by the Company.

This is for your information and dissemination to the members of the exchange.

Thanking you.

Yours sincerely,

FOR GRANULES INDIA LIMITED

CHAITANYA

TUMMALA

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CHAITANYA TUMMALA
Date: 2024.12.17 11:02:31
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**CHAITANYA TUMMALA
COMPANY SECRETARY &
COMPLIANCE OFFICER**



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 Lisdexamphetamine 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. Lisdexamphetamine 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. Lisdexamphetamine 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.

Safe Harbor: This document is to provide general background information about the Company’s activities as at the date of the release. The information contained herein is for general information purposes only and based on estimates and should not be considered as a recommendation that any investor should subscribe / purchase the company shares. The Company makes no representation or warranty, express or implied, as to, and does not accept any responsibility or liability with respect to, the fairness, accuracy, completeness or correctness of any information contained herein. This release may include certain “forward looking statements”. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currencies, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global pharmaceuticals industries, increasing competition, changes in political conditions in India or any other country and changes in the foreign exchange control regulations in India. Neither the company, nor its directors and any of the affiliates or employees have any obligation to update or otherwise revise any forward-looking statements. The readers may use their own judgment and are advised to make their own calculations before deciding on any matter based on the information given herein. No part of this release may be reproduced, quoted or circulated without prior written approval from Granules India Limited.

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