Press Release

Granules Pharmaceuticals, Inc. Receives FDA Tentative Approval with 180-Day Exclusivity for Generic Amphetamine Extended-Release Tablets (gDYANAVEL XR)

Hyderabad, India – January 8, 2026 – Granules Pharmaceuticals, Inc., a wholly owned subsidiary of Granules India Limited, has received Tentative Approval (TA) from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for generic Amphetamine Extended-Release Tablets in strengths of 5 mg, 10 mg, 15 mg, and 20 mg, the generic equivalent of DYANAVEL XR®.

The Granules ANDA has been determined to be **eligible for 180-day exclusivity by the FDA**, reinforcing its growing capabilities in developing and commercializing complex and differentiated generic products for the U.S. market. The product is indicated for the treatment of **Attention Deficit Hyperactivity Disorder (ADHD)** and has **an estimated market size of approximately USD 41 million**.

Granules previously received a tentative approval on December 22nd, 2025 for Amphetamine Extended-Release Orally Disintegrating Tablets in strengths of 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, and 18.8 mg, the generic equivalent of ADZENYS XR-ODT® also for the treatment of ADHD. This product has **only one approved generic and one authorized generic** with an addressable market share of USD 172 million, positioning Granules favourably to expand access to this critical therapy upon launch. The tentative approval of generic gDYANAVEL XR tablets marks the second consecutive approval from Granules' subsidiary, Granules Pharmaceuticals, Inc., within a period of a few weeks.

Commenting on the development, Dr. Krishna Prasad Chigurupati, Chairman & Managing Director, Granules India Limited, said:

"Having a product that is eligible for 180-day exclusivity, Granules strongly validates our long-term strategy of building a differentiated portfolio of complex generics. It also reinforces our commitment to strengthening our presence in the central nervous system (CNS) therapeutic space while enhancing value creation in the U.S. generics market."

This achievement highlights Granules' expanding capabilities in **complex formulation development** and **regulatory execution.** It reinforces the Company's ability to identify, develop, and progress **technically challenging products** that deliver meaningful differentiation and long-term value.

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

Granules India Limited, incorporated in 1991 is a vertically integrated fast growing Indian pharmaceutical company headquartered at Hyderabad with best-in-class facilities and 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 entire value chain – from Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs), Finished Dosages (FDs) and Peptides CDMO. 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, US and Switzerland. The Company has 11 manufacturing facilities out of which 8 are in India, 2 in the USA and 1 in Switzerland and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC, and HALAL. For more information about Granules India Ltd and its initiatives, please visit www.granulesindia.com.

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