Press Release ***For Immediate Release***

Granules India Limited Received ANDA Approval for Sildenafil for Oral Suspension.

- *Granules has a total of 63 ANDA approvals from the US FDA (61 final and 2 tentative approvals)*

- *Sildenafil for Oral Suspension is indicated for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability and delay clinical worsening.*

Hyderabad, 03 December 2023: Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA), filed by Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the company, for Sildenafil for Oral Suspension, 10 mg/mL. It is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Revatio for Oral Suspension, 10mg/ml, of Viatris Specialty LLC.

Sildenafil for Oral Suspension is indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

Granules now has a total of 63 ANDA approvals from the US FDA (61 final approvals and 2 tentative approvals).

The current annual U.S. market for Sildenafil for Oral Suspension is approximately $43 million, according to MAT Sep 2023, IQVIA/IMS Health.

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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) 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 7 manufacturing facilities out of which 6 are located in India and 1 in USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL. Get more information https://granulesindia.com

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