Press Release ***For Immediate Release***

Granules India Limited Received ANDA Approval for Pantoprazole Sodium Delayed-Release Tablets.

- *Granules has a total of 64 ANDA approvals from the US FDA (62 final and 2 tentative approvals).*

- *Pantoprazole Sodium Delayed-Release Tablets are indicated for short-term Treatment of Erosive Esophagitis Associated with Gastroesophageal Reflux Disease (GERD).*

Hyderabad, 13 December 2023: Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Pantoprazole Sodium Delayed-Release Tablets USP, 20 mg and 40 mg. It is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Protonix Delayed-Release Tablets, 20 mg and 40 mg, of Wyeth Pharmaceuticals LLC.

Pantoprazole Sodium Delayed-Release Tablets are indicated for short-term Treatment of Erosive Esophagitis Associated with Gastroesophageal Reflux Disease (GERD), Maintenance of Healing of Erosive Esophagitis and Pathological Hypersecretory Conditions Including Zollinger-Ellison (ZE) Syndrome.

Granules now has a total of 64 ANDA approvals from the US FDA (62 final approvals and 2 tentative approvals).

The current annual U.S. market for Pantoprazole Tablets is approximately $233 million, according to IQVIA/IMS Health, MAT Oct 2023.

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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 at https://granulesindia.com

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