Press Release *For Immediate Release*

Granules India Limited Received ANDA Approval for Guaifenesin and Pseudoephedrine Hydrochloride Extended-Release Tablets

Hyderabad, 26 August 2022: Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Guaifenesin and Pseudoephedrine Hydrochloride Extended-Release (ER) Tablets, 600 mg/60 mg and 1200 mg/120 mg (OTC). It is bioequivalent to the reference listed drug product, Mucinex D Extended-Release Tablets, 600 mg/60 mg and 1200 mg/120 mg, of RB Health (US) LLC.

Guaifenesin and Pseudoephedrine Hydrochloride ER Tablets are used to loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive; temporarily relieve nasal congestion due to common cold, hay fever, upper respiratory allergies; temporarily restores freer breathing through the nose; promotes nasal and/or sinus drainage; and temporarily relieves sinus congestion and pressure.

Granules now have a total of 51 ANDA approvals from US FDA (49 Final approvals and 2 tentative approvals).

The Mucinex® D brand and store brands had combined U.S. sales of approximately $71 million MAT for the most recent twelve months.

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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, US and UK. The Company has 7 manufacturing facilities out of which 6 are 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.