REGISTERED OFFICE

GRANULES INDIA LTD., 2nd Floor, 3rd Block, My Home Hub,
Madhapur, Hyderabad – 500 081, Telangana, INDIA.
Tel: +91 40 69043500, Fax: +91 40 23115145, mail@granulesindia.com, www.granulesindia.com
CIN: L24110TG1991PLC012471
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Dated August 26, 2022

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

Digitally signed by CHAITANYA TUMMALA
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Date: 2022.08.26 10:50:27 +05'30'

GRANULES INDIA LIMITED Hyderabad

CHAITANYA TUMMALA
(COMPANY SECRETARY &
COMPLIANCE OFFICER)

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.

END

Contact:

Krishna Raghunathan Vice President – Finance and Investor Relations 040-69043573 krishna.raghunathan@granulesindia.com	**Chaitanya Tummala** Company Secretary 040-69043614 chaitanya.tummala@granulesindia.com

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.