



Press Release

For Immediate Release

Granules India Limited announces approval of Penicillamine Capsules, 250 mg, generic equivalent of Cuprimine[®] of Bausch Health Americas, Inc.

Date: 3rd December, 2020

Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved the Abbreviated New Drug Application (ANDA) filed by Granules Pharmaceuticals, Inc (GPI), a wholly owned foreign subsidiary of Granules India Limited, for Penicillamine Capsules USP, 250 mg. It is bioequivalent to the reference listed drug product (RLD), Cuprimine[®] of Bausch Health Americas, Inc. The product would be manufactured at Granules manufacturing facility in Chantilly, Virginia and is expected to be launched shortly.

Penicillamine Capsules are indicated in the treatment of Wilson's disease, cystinuria, and in patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy.

Granules now has a total of 35 ANDA approvals from US FDA (33 Final approvals and 2 tentative approvals).

Penicillamine Capsules had U.S. sales of approximately \$67 million for the most recent twelve months ending in October 2020 according to IQVIA Health.

Cuprimine[®] is a trademark of Bausch Health Companies Inc. or its affiliates.

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

Granules India is a growing pharmaceutical manufacturing company with best-in-class facilities and is committed to operational excellence, quality and customer service. The Company produces Finished Dosages (FDs), Pharmaceutical Formulation Intermediates (PFIs) and Active Pharmaceutical Ingredients (APIs) which gives the customers flexibility and choice. Granules support customers with unique value, extensive product range, and proactive solutions. The Company's global presence extends to over 250 customers in 60 countries through offices in India, U.S., and U.K. The Company has 6 manufacturing facilities out of which 5 are located in India and 1 in USA. Five of these have regulatory approvals from the USFDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.



Investor Contacts:

Sandip Neogi

Chief Financial Officer

040-30663563

sandip.neogi@granulesindia.com

Chaitanya Tummala

Company Secretary

040-30663614

chaitanya.tummala@granulesindia.com

Safe Harbor:

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This release may include certain "forward looking statements". These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currencies, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global pharmaceuticals industries, increasing competition, changes in political conditions in India or any other country and changes in the foreign exchange control regulations in India. Neither the company, nor its directors and any of the affiliates or employee have any obligation to update or otherwise revise any forward-looking statements. The readers may use their own judgment and are advised to make their own calculations before deciding on any matter based on the information given herein.

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