Press Release

Granules India Limited announces tentative approval of Colchicine Capsules, 0.6 mg, generic equivalent of Mitigare® Capsules, 0.6mg of Hikma International Pharmaceuticals LLC.

Hyderabad, February 11, 2020

Granules India Limited announced today that the US Food & Drug Administration (US FDA) has tentatively approved the Abbreviated New Drug Application (ANDA) filed by Granules Pharmaceuticals, Inc (GPI)., a wholly owned foreign subsidiary of Granules India Limited for Colchicine Capsules, 0.6 mg. It is bioequivalent to the reference listed drug product (RLD), Mitigare Capsules, 0.6 mg, of Hikma International Pharmaceuticals LLC.

"We are pleased to receive tentative approval for our 4th Paragraph IV ANDA and launch of the product will be as per our agreement with Hikma Pharmaceuticals USA Inc.," said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc., commenting on the approval.

Granules now has a total of 22 ANDA approvals from US FDA (21 Final approvals and 1 tentative approval).

Colchicine capsules are indicated for prophylaxis of gout flares in adults.

The Mitigare® brand and generic had U.S. sales of approximately $84 million MAT for the most recent twelve months ending in December 2019 according to IQVIA Health.

Mitigare® is a registered trademark of Hikma Pharmaceuticals USA Inc.

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 and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.

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