Press Release

Granules India Limited receives approval from US Food & Drug Administration (US FDA) of Colchicine Tablets used for the treatment of Familial Mediterranean Fever (FMF).

Hyderabad, February 6, 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 Colchicine Tablets USP, 0.6 mg. It is bioequivalent to the reference listed drug product (RLD), Colcrys Tablets, 0.6 mg, of Takeda Pharmaceuticals USA, Inc. This marks the second Paragraph IV ANDA approval for Granules.

Colcrys® is a trademark of Takeda Pharmaceuticals USA, Inc. Colchicine Tablets are used for the treatment of Familial Mediterranean Fever (FMF).

The Colcrys® brand and generic had U.S. sales of approximately $492 million MAT for the most recent twelve months ending in December 2019 according to IQVIA Health.

"With back to back two Paragraph IV ANDA approvals in this week; we received total 8 approvals for ANDAs filed by GPI. This demonstrates the capability of GPI, confirming our investment strategy in this facility" said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc., commenting on the approval.

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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