Press Release ***For Immediate Release***

Granules India Limited announces US FDA approval OTC (Store brand) equivalent of Advil® Dual Action Tablets.

Granules India has a total of 59 ANDA approvals from the US FDA (57 Final and 2 tentative approvals)

Acetaminophen and Ibuprofen Tablets are used for temporary relief from minor aches and pains due to headaches, toothaches, backaches, menstrual cramps, muscular aches, and minor arthritis

Hyderabad, 14 July 2023: Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA), filed by Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the company, for Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg (OTC). It is bioequivalent to the reference listed drug (RLD), Advil® Dual Action with Acetaminophen Tablets, 250mg/125 mg (OTC), of GlaxoSmithKline Consumer Healthcare Holdings (US) LLC. This product will be launched through the Granules Consumer Health (GCH) division.

Acetaminophen and Ibuprofen Tablets are used for temporary relief of minor aches and pains due to headaches, toothaches, backaches, menstrual cramps, muscular aches, and minor arthritis pain.

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According to IRI multi-outlet market data, the Advil® Dual Action with Acetaminophen Tablets (OTC) brand and store brands had combined US sales of approximately $70 million in the most recent twelve months.

Advil® is a registered trademark of GlaxoSmithKline Consumer Healthcare Holdings (US).

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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 in Hyderabad with best-in-class facilities and a commitment to operational excellence, quality, and customer service. Amongst the few pharmaceutical companies in the world to be present across the manufacturing of the entire pharmaceutical value chain – from Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs) and Finished Dosages (FDs), Granules products are 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 8 manufacturing facilities out of which 6 are located in India and 2 are in USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL. Get more information: https://granulesindia.com