Granules India Limited Announces ANDA Approval for Bupropion Hydrochloride Extended-Release Tablets

Hyderabad, 18th October 2024: Granules India Limited announced today that the U.S. Food & Drug Administration (USFDA) has approved the Abbreviated New Drug Application (ANDA) for Bupropion Hydrochloride Extended-Release Tablets USP (SR) 100 mg, 150 mg, and 200 mg filed by Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the Company.

Bupropion Hydrochloride Extended-Release Tablets USP (SR) are bioequivalent and therapeutically equivalent to Wellbutrin SR Sustained-Release Tablets, 100 mg, 150 mg, and 200 mg, by GlaxoSmithKline LLC. This is a widely prescribed medication for the treatment of major depressive disorder and for the prevention of seasonal affective disorder.

Granules now has a total of 67 ANDA approvals from the US FDA.

Dr. Krishna Prasad Chigurupati, Chairman and Managing Director, Granules India Limited, said, "*This ANDA approval marks a significant milestone in our journey to expand Granules' presence in the U.S. market. Our continued focus on expanding our product portfolio in regulated markets like the U.S. ensures that we are meeting the growing healthcare needs of patients globally, while maintaining the highest standards of safety and efficacy.*

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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 10 manufacturing facilities out of which 8 are located in India and 2 are in the USA and has regulatory approvals from the US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC, and HALAL. Get more information: https://granulesindia.com

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