REGISTERED OFFICE

GRANULES INDIA LTD., 2nd Floor, 3rd Block, My Home Hub,
Madhapur, Hyderabad – 500 081, Telangana, INDIA.
Tel: +91 40 30660000, Fax: +91 40 23115145, mail@granulesindia.com, www.granulesindia.com
CIN: L24110TG1991PLC012471

Dated April 27, 2020

To,
National Stock Exchange of India Limited
BSE Limited
Symbol: NSE: GRANULES; BSE: 532482

Sub: Press Release

Dear Sir,

We are herewith enclosing the press release given by the Company.

This is for your information and dissemination to the members of the exchange.

Thanking You.

Yours sincerely,

For GRANULES INDIA LIMITED

CHAITANYA TUMMALA
(COMPANY SECRETARY &
COMPLIANCE OFFICER)
Encl as above

Press Release

Granules India Limited announces approval of Vigabatrin for Oral Solution USP, 500 mg

Hyderabad, April 27, 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 Vigabatrin for Oral Solution USP, 500 mg. It is bioequivalent to the reference listed drug product (RLD), Sabril® (vigabatrin) for Oral Solution, 500 mg, of Lundbeck Pharmaceuticals LLC.

Vigabatrin for Oral Solution is indicated as adjunctive therapy for adults and pediatric patients 2 years of age and older with refractory complex partial seizures who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Vigabatrin for Oral Solution is not indicated as a first line agent for complex partial seizures.

Vigabatrin for Oral Solution is also indicated as monotherapy for pediatric patients with infantile spasms 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

“We are delighted to announce approval of our first specialty product, which also happens to be our first product approved in sachet (for oral solution) dosage form. It reiterates our strategy and capability for delivering diversified product portfolio in the US market. We are happy to see two ANDA approvals within one week” said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc., commenting on the approval.

Vigabatrin for Oral Solution (brand and generic) products had U.S. sales of approximately $255 million MAT for the most recent twelve months ending in February 2020 according to IQVIA Health.

Granules now has a total of 27 ANDA approvals from US FDA (25 Final approvals and 2 tentative approvals).

The Granules generic product received FDA approval under a Risk Evaluation and Mitigation Strategy (REMS) known as the Vigabatrin REMS program. Information on this program is available at https://www.vigabatrinrems.com/ or +1 866-244-8175. See full prescribing information for complete boxed warning.

Sabril® is a registered trademark of Lundbeck

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.

Contacts:

Sandip Neogi
Chief Financial Officer
040-30663572
sandip.neogi@granulesindia.com

Chaitanya Tummala
Company Secretary
040-30663614
chaitanya.tummala@granulesindia.com

Safe Harbour

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