REGISTERED OFFICE

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CIN: L24110TG1991PLC012471

Dated: October 18, 2021

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

Ref: Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

Dear Sir,

Please be informed 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 the Company, for Dofetilide Capsules, 125 mcg, 250 mcg, and 500 mcg. It is bioequivalent to the reference listed drug product (RLD), Tikosyn* Capsules, 125 mcg, 250 mcg, and 500 mcg, of Pfizer Inc. This product would be manufactured at the GPI facility located in Chantilly, Virginia, USA and is expected to be launched shortly.

Dofetilide capsules are indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation) in patients with atrial fibrillation/atrial flutter of greater than one week duration who have been converted to normal sinus rhythm. They are also indicated for the conversion of atrial fibrillation and atrial flutter to normal sinus rhythm.

Granules now has a total of 45 ANDA approvals from US FDA (43 Final approvals and 2 tentative approvals).

Dofetilide Capsule products had U.S. sales of approximately $39 million for the most recent twelve months ending in August 2021 according to IQVIA Health.

*Tikosyn is a registered trademark of Pfizer, Inc.

This is for your information and dissemination to the members of the exchange.
Thanking You.
Yours sincerely,

For GRANULES INDIA LIMITED

T. Chaitanya.

GRANULES INDIA LIMITED Hyderabad

CHAITANYA TUMMALA
(COMPANY SECRETARY &
COMPLIANCE OFFICER)