Date: 14th March, 2022

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Tentative Approval for Macitentan Tablets, 10 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Tentative Approval for Macitentan Tablets, 10 mg.

Please find enclosed herewith our press release.

We request you to kindly take the same on record.

Thanking you,

Yours faithfully,
For Alembic Pharmaceuticals Limited

Charandeep Singh Saluja
Company Secretary

Encl.: A/a.

PRESS RELEASE

14th March, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Macitentan Tablets, 10 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Macitentan Tablets, 10 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Opsumit Tablets, 10 mg, of Actelion Pharmaceuticals US, Inc. (Actelion). Macitentan Tablets are an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression. Disease progression included: death, initiation of intravenous (IV) or subcutaneous prostanoids, or clinical worsening of PAH (decreased 6-minute walk distance, worsened PAH symptoms and need for additional PAH treatment). Macitentan Tablets also reduced hospitalization for PAH. It may not be indicated for certain other uses due to unexpired exclusivities for the RLD for such uses.

Macitentan Tablets, 10 mg have an estimated market size of US$ 797 million for twelve months ending Dec 2021 according to IQVIA.

Alembic has received year to date (YTD) 22 approvals (15 final approvals and 7 tentative approvals) and a cumulative total of 161 ANDA approvals (138 final approvals and 23 tentative approvals) from USFDA.

About Alembic Pharmaceuticals Limited

Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, has been at the forefront of healthcare since 1907. Headquartered in India, Alembic is a publicly listed company that manufactures and markets generic pharmaceutical products all over the world. Alembic's state of the art research and manufacturing facilities are approved by regulatory authorities of many developed countries including the USFDA. Alembic is one of the leaders in branded generics in India. Alembic's brands, marketed through a marketing team of over 5000 are well recognized by doctors and patients.

Information about Alembic can be found at https://www.alembicpharmaceuticals.com; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

For more information contact:

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