Alembic
Touching Lives over 100 years

Date: 16th June, 2020

To,
The Manager,
Listing Department
National Stock Exchange of India Ltd.
'Exchange Plaza'
Bandra Kurla Complex, Bandra (E),
Mumbai – 400 051

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Deferasirox Tablets, 180 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Final Approval for Deferasirox Tablets, 180 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.

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PRESS RELEASE

16th June, 2020, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Deferasirox Tablets, 180 mg.

Alembic Pharmaceuticals Limited today announced that the Company has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Deferasirox Tablets, 180 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Jadenu Tablets, 180 mg, of Novartis Pharmaceuticals Corporation (Novartis). Deferasirox tablets are indicated for treatment of Chronic Iron Overload Due to Blood Transfusions (Transfusional Iron Overload) and for treatment of Chronic Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes. Alembic had previously received final approval for Deferasirox Tablets, 90 mg and 360 mg and tentative approval for Deferasirox Tablets, for 180 mg.

Deferasirox Tablets, 180 mg have an estimated market size of US$ 53 million for twelve months ending March 2020 according to IQVIA.

Alembic now has a total of 122 ANDA approvals (109 final approvals and 13 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 http://www.alembicpharmaceuticals.com/; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

For more information contact:

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