Alembic
Touching Lives over 100 years

Date: 2nd July, 2019

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 Approval for Febuxostat Tablets, 40 mg and 80 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Approval for Febuxostat Tablets, 40 mg and 80 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

2nd July 2019, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Febuxostat Tablets, 40 mg and 80 mg.

Alembic Pharmaceuticals Limited today announced that the Company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Febuxostat Tablets, 40 mg and 80 mg. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Uloric Tablets, 40 mg and 80 mg, of Takeda Pharmaceuticals U.S.A., Inc. (Takeda). Febuxostat Tablets are xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable. Febuxostat Tablets are not recommended for the treatment of asymptomatic hyperuricemia.

Febuxostat Tablets have an estimated market size of US$ 578 million for twelve months ending December 2018 according to IQVIA.

Alembic had previously received tentative approval for this ANDA.

Alembic now has a total of 98 ANDA approvals (87 final approvals and 11 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 the company 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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