Alembic
Touching Lives over 100 years

Date: 23rd January, 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 Fenofibrate Tablets USP, 54 mg and 160 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 Fenofibrate Tablets USP, 54 mg and 160 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

23rd January, 2020, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Fenofibrate Tablets USP, 54 mg and 160 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Fenofibrate Tablets USP, 54 mg and 160 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Tricor Tablets, 54 mg and 160 mg, of AbbVie Inc. (AbbVie). Fenofibrate Tablets USP, 54 mg and 160 mg are indicated as an adjunct to diet to reduce elevated LDL-C, Total-C, TG and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidaemia and for treatment of adult patients with severe hypertriglyceridemia.

Fenofibrate Tablets USP, 54 mg and 160 mg have an estimated market size of US$ 100 million for twelve months ending September 2019 according to IQVIA.

Alembic has a cumulative total of 113 ANDA approvals (100 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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