Alembic
Touching Lives over 100 years

Date: 1st 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 Clonazepam Orally Disintegrating Tablets USP, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 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 Clonazepam Orally Disintegrating Tablets USP, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 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

1st July 2019, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Clonazepam Orally Disintegrating Tablets USP, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 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) Clonazepam Orally Disintegrating Tablets USP, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Klonopin Orally Disintegrating Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 1 mg and 2 mg, of Hoffmann-La Roche, Inc. (Roche). Clonazepam orally disintegrating tablet is useful alone or as an adjunct in the treatment of the Lennox-Gastaut syndrome (petit mal variant), akinetic and myoclonic seizures. In patients with absence seizures (petit mal) who have failed to respond to succinimides, clonazepam orally disintegrating tablets may be useful. It is also indicated for the treatment of panic disorder, with or without agoraphobia, as defined in DSM-V.

Clonazepam Orally Disintegrating Tablets USP has an estimated market size of US$ 20 million for twelve months ending December 2018 according to IQVIA.

Alembic now has a total of 98 ANDA approvals (86 final approvals and 12 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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