Alembic
Touching Lives over 100 years

Date: 29th 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 Approvals for Azithromycin Tablets USP, 250 mg and 500 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Final Approvals for Azithromycin Tablets USP, 250 mg and 500 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

29th January, 2020, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approvals for Azithromycin Tablets USP, 250 mg and 500 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced it has received final approvals from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Applications (ANDAs) Azithromycin Tablets USP, 250 mg and 500 mg. The approved ANDAs are therapeutically equivalent to the reference listed drug products (RLDs), Zithromax Tablets, 250 mg and 500 mg, of Pfizer, Inc. (Pfizer). Azithromycin Tablet is a macrolide antibacterial drug indicated for mild to moderate infections caused by designated, susceptible bacteria in acute bacterial exacerbations of chronic bronchitis in adults; acute bacterial sinusitis in adults; uncomplicated skin and skin structure infections in adults; urethritis and cervicitis in adults; genital ulcer disease in men; acute otitis media in pediatric patients; community-acquired pneumonia in adults and pediatric patients; and pharyngitis/tonsillitis in adults and pediatric patients.

Azithromycin Tablets USP, 250 mg and 500 mg have an estimated market size of US$ 129 million for twelve months ending September 2019 according to IQVIA.

Alembic has a cumulative total of 117 ANDA approvals (105 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 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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