

PRESS RELEASE

10th July, 2017, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Dabigatran Etexilate Capsules, 150 mg.

Alembic Pharmaceuticals Limited today announced that the company has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Dabigatran Etexilate Capsules, 150 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) PRADAXA® Dabigatran Etexilate Mesylate Capsules, Eq to 150 mg base, Boehringer Ingelheim. Dabigatran Etexilate Capsules are indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, and for the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been treated with a parenteral anticoagulant for 5 to 10 days. It is also indicated to reduce the risk of recurrence of DVT and PE in patients who have been previously treated.

Dabigatran Etexilate Capsules, 150 mg have an estimated market size of US\$ 726.3 million for twelve months ending December 2016 according to IMS.

Alembic now has a total of 60 ANDA approvals (52 final approvals and 8 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: APL LTD) (BSE: 533573)

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