PRESS RELEASE

10th January, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Dronedarone Tablets USP, 400 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Dronedarone Tablets USP, 400 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Multaq Tablets, 400 mg, of Sanofi-Aventis U.S. LLC (Sanofi-Aventis). Dronedarone is indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

Dronedarone Tablets USP, 400 mg have an estimated market size of US$ 500 million for twelve months ending September 2021 according to IQVIA. Alembic has settled the case with Sanofi-Aventis and will launch its generic as per the terms of settlement.

Alembic has received year to date (YTD) 19 approvals (13 final approvals and 6 tentative approvals) and a cumulative total of 158 ANDA approvals (136 final approvals arid 22 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)

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