PRESS RELEASE

19th August, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Macitentan Tablets, 10 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Macitentan Tablets, 10 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Opsumit Tablets, 10 mg, of Actelion Pharmaceuticals US, Inc. (Actelion).

Macitentan tablets are an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) in adults to reduce the risks of disease progression and hospitalization for PAH. Refer label for a detailed indication.

Macitentan Tablets, 10 mg, have an estimated market size of US$ 1,180 million for twelve months ending June 2025 according to IQVIA.

Alembic has a cumulative total of 224 ANDA approvals (203 final approvals and 21 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 field force of over 5500 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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