

PRESS RELEASE

4th July, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Tentative Approval for Ivosidenib Tablets 250 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 Ivosidenib Tablets, 250 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Tibsovo Tablets, 250 mg, of Servier Pharmaceuticals LLC (Servier).

Ivosidenib is an isocitrate dehydrogenase-1 (IDH1) inhibitor indicated for patients with a susceptible IDH1 mutation as detected by an FDA-approved test with: (a) Newly Diagnosed Acute Myeloid Leukemia (AML) as monotherapy in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy (b) Adult patients with Relapsed or refractory AML (c) Adult patients with Locally Advanced or Metastatic Cholangiocarcinoma who have been previously treated.

Ivosidenib Tablets, 250 mg have an estimated market size of US\$ 114 million for twelve months ending March 2024 according to IQVIA.

Alembic has a cumulative total of 207 ANDA approvals (179 final approvals and 28 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 <https://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

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ALEMBIC PHARMACEUTICALS LIMITED