

2nd May, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Ticagrelor Tablets, 90 mg and Tentative Approval for Ticagrelor Tablets, 60 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) Ticagrelor Tablets, 90 mg and tentative approval for Ticagrelor Tablets, 60 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Brilinta Tablets, 60 mg and 90 mg, of AstraZeneca Pharmaceuticals LP (AstraZeneca). Ticagrelor tablets are indicated for: i) to reduce the risk of cardiovascular (CV) death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of MI. For at least the first 12 months following ACS, it is superior to clopidogrel. Ticagrelor tablets also reduces the risk of stent thrombosis in patients who have been stented for treatment of ACS. ii) to reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events, and iii) to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score <5) or high-risk transient ischemic attack (TIA). Refer label for a detailed indication.

For Ticagrelor Tablets, 90 mg, Alembic was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification.

Ticagrelor Tablets, 90 mg have an estimated market size of US\$ 1,062 million for twelve months ending March 2025 according to IQVIA. Ticagrelor Tablets, 60 mg have an estimated market size of US\$ 242 million for twelve months ending March 2025 according to IQVIA.

Alembic has a cumulative total of 222 ANDA approvals (197 final approvals and 25 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 5200 are well recognized by doctors and patients.

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

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