Alembic Pharma Gets USFDA Nod for Generic Cancer Drug Venetoclax



New Delhi: Alembic Pharmaceuticals Limited (Alembic) has announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Venetoclax Tablets, 10 mg, 50 mg and 100 mg.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Venclexta Tablets, 10 mg, 50 mg, and 100 mg, of AbbVie Inc. (AbbVie).

Venetoclax tablets are indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Venetoclax tablets are also indicated, in combination with azacitidine, or decitabine, or low-dose cytarabine, for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. Refer label for a detailed indication and usage.

Alembic was a first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Venetoclax Tablets, 10 mg, 50 mg and 100 mg. Therefore, with this approval, Alembic may be eligible for 180 days of generic drug exclusivity.

According to IQVIA, Venetoclax tablets, 10 mg, 50 mg and 100 mg, had an estimated market size of US $1,584 million in the United States for twelve months ending June 2026.

Alembic has a cumulative total of 248 ANDA approvals (228 final approvals and 20 tentative approvals) from the USFDA.

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 5,800 are well recognized by doctors and patients.

News Source:

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