

**PRESS RELEASE**

19<sup>th</sup> January, 2023, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Tentative Approval for Acalabrutinib Capsules, 100 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), Acalabrutinib Capsules, 100 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Calquence Capsules, 100 mg, of AstraZeneca UK Limited (AstraZeneca). Acalabrutinib Capsules are indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy and treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Acalabrutinib Capsules, 100 mg, have an estimated market size of US\$1.5billion for twelve months ending Sep 2022 according to IQVIA.

Alembic has a cumulative total of 180 ANDA approvals (157 final approvals and 23 tentative approvals) from USFDA.

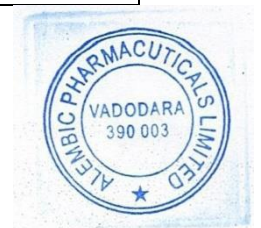
**About Alembic Pharmaceuticals Limited**

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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