PRESS RELEASE

2nd November, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Mesalamine Extended-Release Capsules USP, 0.375 g.

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) for Mesalamine Extended-Release Capsules USP, 0.375 g. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Apriso Extended-Release Capsules, 0.375 g, of Salix Pharmaceuticals, Inc. (Salix). Mesalamine Extended-Release Capsules are indicated for the maintenance of remission of ulcerative colitis in adults.

Mesalamine Extended-Release Capsules USP, 0.375 g, have an estimated market size of US$ 133 million for twelve months ending June 2022 according to IQVIA.

Alembic has a cumulative total of 174 ANDA approvals (150 final approvals and 24 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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