PRESS RELEASE

26th December, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) per Single-Dose Prefilled Syringe.

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), Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) per Single-Dose Prefilled Syringe. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Faslodex Injection, 250 mg/5 mL (50 mg/mL), of AstraZeneca Pharmaceuticals LP. Fulvestrant Injection is an estrogen receptor antagonist indicated for the treatment of breast cancer. Refer to our label for full indication.

Fulvestrant Injection, 250 mg/5 mL, has an estimated market size of US$71 million for twelve months ending Sep 2022 according to IQVIA.

Alembic has received a cumulative total of 179 ANDA approvals (156 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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