PRESS RELEASE

27th September, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Paliperidone Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 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) Paliperidone Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Invega Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg, of Janssen Pharmaceuticals, Inc. (Janssen). Paliperidone extended-release tablets are an atypical antipsychotic agent indicated for Treatment of schizophrenia and it is also indicated for treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressants. Refer label for a detailed indication.

Paliperidone Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg have an estimated market size of US$ 48 million for twelve months ending June 2024 according to IQVIA.

Alembic has a cumulative total of 215 ANDA approvals (187 final approvals and 28 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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