1st April, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Pantoprazole Sodium for Injection, 40 mg/vial (Single-Dose Vial)

Alembic Pharmaceuticals Limited (Alembic) announced that it has received Final Approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDAPantoprazole Sodium for Injection, 40 mg/vial (Single-Dose Vial). The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Protonix I.V. for Injection, 40 mg/vial, of Wyeth Pharmaceuticals LLC. Pantoprazole sodium for injection is indicated for treatment of gastroesophageal reflux disease (GERD) and a history of erosive esophagitis (EE) for up to 10 days in adults. It is also indicated for the treatment of pathological hypersecretion conditions including Zollinger-Ellison (ZE) Syndrome in adults. Refer label for a detailed indication.

Pantoprazole Sodium for Injection, 40 mg/vial (Single-Dose Vial) have an estimated market size of US$ 48 million for twelve months ending December 2024 according to IQVIA.

Alembic has a cumulative total of 221 ANDA approvals (195 final approvals and 26 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 field force of over 5200 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

For more information, contact:
Ajay Kumar Desai
Phone: +91 22-66953681
Email: ajay.desai@alembic.co.in