**PRESS RELEASE**

2nd August, 2024, Vadodara, India

**Alembic Pharmaceuticals announces USFDA Final Approval for Nelarabine Injection, 250 mg/50 mL (5 mg/mL) (Single-Dose Vial).**

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 Nelarabine Injection, 250 mg/50 mL (5 mg/mL) (Single-Dose Vial). The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Arranon Injection, 250 mg/50 mL (5 mg/mL), of Sandoz Inc. Nelarabine is a nucleoside metabolic inhibitor indicated for the treatment of patients with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma in adult and pediatric patients age 1 year and older whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. Refer label for a detailed indication.

Nelarabine Injection, 250 mg/50 mL has an estimated market size of US$ 23 million for twelve months ending March 2024 according to IQVIA.

Alembic has a cumulative total of 211 ANDA approvals (183 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)

For more information contact:
Ajay Kumar Desai

Phone: +91 22-66953681| 7045504460
Email: ajay.desai@alembic.co.in