PRESS RELEASE

06th February, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Carbidopa, Levodopa and Entacapone Tablets.

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) Carbidopa, Levodopa and Entacapone Tablets, 12.5 mg/50 mg/200 mg, 18.75 mg/75 mg/200 mg, 25 mg/100 mg/200 mg, 31.25 mg/125 mg/200 mg, 37.5 mg/150 mg/200 mg, and 50 mg/200 mg/200 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Stalevo Tablets, 12.5 mg/50 mg/200 mg, 18.75 mg/75 mg/200 mg, 25 mg/100 mg/200 mg, 31.25 mg/125 mg/200 mg, 37.5 mg/150 mg/200 mg, and 50 mg/200 mg/200 mg, of Orion Corporation. Carbidopa, levodopa and entacapone tablets are indicated for the treatment of Parkinson's disease. Refer label for a detailed indication.

Alembic has a cumulative total of 234 ANDA approvals (214 final approvals and 20 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 5500 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)

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