PRESS RELEASE

6th January, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Entacapone Tablets USP, 200 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) for Entacapone Tablets USP, 200 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Comtan Tablets, 200 mg, of Orion Corporation. Entacapone Tablets are indicated as an adjunct to levodopa and carbidopa to treat end-of-dose "wearing-off" in patients with Parkinson's disease.

Entacapone Tablets USP, 200 mg have an estimated market size of US$ 10.5 million for twelve months ending September 2021 according to IQVIA.

Alembic has received year to date (YTD) 17 approvals (13 final approvals and 4 tentative approvals) and a cumulative total of 156 ANDA approvals (136 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 marketing team of over 5000 are well recognized by doctors and patients.

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

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