PRESS RELEASE

14th September, 2018, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Alogliptin and Metformin Hydrochloride Tablets, 12.5 mg/500 mg and 12.5 mg/1000 mg.

Alembic Pharmaceuticals Limited today announced that the company has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Alogliptin and Metformin Hydrochloride Tablets, 12.5 mg/500 mg and 12.5 mg/1000 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), KAZANO® Tablets, 12.5 mg/500 mg and 12.5 mg/1000 mg of Takeda Pharma USA. Alogliptin and Metformin Hydrochloride Tablets, 12.5 mg/500 mg and 12.5 mg/1000 mg are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both alogliptin and metformin is appropriate.

Alogliptin and Metformin Hydrochloride Tablets, 12.5 mg/500 mg and 12.5 mg/1000 mg has an estimated market size of US$ 22.5 million for twelve months ending December 2017 according to IQVIA.

Alembic now has a total of 77 ANDA approvals (64 final approvals and 13 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 the company can be found at http://www.alembicpharmaceuticals.com/; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

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