

**PRESS RELEASE**

16<sup>th</sup> October, 2018, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Tentative Approval for Alogliptin Tablets, 6.25 mg, 12.5 mg and 25 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) Alogliptin Tablets, 6.25 mg, 12.5 mg and 25mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), NESINA® Tablets, 6.25 mg, 12.5 mg and 25mg of Takeda Pharms USA. Alogliptin Tablets, 6.25 mg, 12.5 mg and 25mg are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Alogliptin Tablets, 6.25 mg, 12.5 mg and 25mg has an estimated market size of US\$ 65.6 million for twelve months ending December 2017 according to IQVIA.

Alembic now has a total of 78 ANDA approvals (64 final approvals and 14 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: APLLED) (BSE: 533573)

For more information contact:

Ajay Kumar Desai	Mitanshu Shah
Phone: +91 22 - 306 11681	Phone: +91 265 - 3007630
Email: <a href="mailto:ajay.desai@alembic.co.in">ajay.desai@alembic.co.in</a>	Email: <a href="mailto:mitanshu.shah@alembic.co.in">mitanshu.shah@alembic.co.in</a>



**ALEMBIC PHARMACEUTICALS LIMITED**

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880 • FAX : (0265) 2281229  
website : [www.alembicpharmaceuticals.com](http://www.alembicpharmaceuticals.com) • E-mail : [alembic@alembic.co.in](mailto:alembic@alembic.co.in) • CIN : L24230GJ2010PLC061123