

**PRESS RELEASE**

22<sup>nd</sup> April, 2019, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Approval for Teriflunomide Tablets, 7 mg and 14 mg.**

Alembic Pharmaceuticals Limited today announced that the company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Teriflunomide Tablets, 7 mg and 14 mg. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Aubagio Tablets, 7 mg and 14 mg, of Sanofi-Aventis U.S., LLC (Sanofi-Aventis). Teriflunomide tablets are indicated for the treatment of patients with relapsing forms of multiple sclerosis.

Teriflunomide Tablets, 7 mg and 14 mg have an estimated market size of US\$ 1.6 billion for twelve months ending December 2018 according to IQVIA. Alembic has settled the litigation and will launch the product as per the terms of the settlement.

Alembic now has a total of 91 ANDA approvals (79 final approvals and 12 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)

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