

PRESS RELEASE

5th July, 2016, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Febuxostat Tablets

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 Febuxostat Tablets, 40 mg and 80 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Uloric® Tablets, 40 mg and 80 mg of Takeda Pharmaceuticals USA, Inc. Febuxostat Tablets are indicated for the chronic management of hyperuricemia in patients with gout.

Uloric® had an estimated market size of US\$ 430 million for twelve months ending December 2015 according to IMS.

Alembic has settled the case with Takeda and will launch its generic as per the terms of the settlement.

Alembic now has a total of 48 ANDA approvals (43 Final approvals and 5 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 US FDA. 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 www.alembic-india.com; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APL LTD) (BSE: 533573)

For more information contact:

Ajay Kumar Desai Phone: +91 22 – 306 11681 Email: ajay.desai@alembic.co.in	Mitanshu Shah Phone: +91 265 – 3007630 Email: mitanshu.shah@alembic.co.in
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