

**PRESS RELEASE**

2<sup>nd</sup> February, 2022, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Tentative Approval for Fesoterodine Fumarate Extended-Release Tablets, 4 mg and 8 mg.**

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Fesoterodine Fumarate Extended-Release Tablets, 4 mg and 8 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Toviaz Extended-Release Tablets, 4 mg and 8 mg, of Pfizer Inc. (Pfizer). Fesoterodine Fumarate Extended-Release Tablets are indicated for the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency. It may not be indicated for certain other uses due to unexpired exclusivities for the RLD for such uses.

Fesoterodine Fumarate Extended-Release Tablets, 4 mg and 8 mg have an estimated market size of US\$ 225 million for twelve months ending September 2021 according to IQVIA.

Alembic has received year to date (YTD) 20 approvals (14 final approvals and 6 tentative approvals) and a cumulative total of 159 ANDA approvals (137 final approvals and 22 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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