

**PRESS RELEASE**

14<sup>th</sup> March, 2022, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Tentative Approval for Macitentan Tablets, 10 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 Macitentan Tablets, 10 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Opsumit Tablets, 10 mg, of Actelion Pharmaceuticals US, Inc. (Actelion). Macitentan Tablets are an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression. Disease progression included: death, initiation of intravenous (IV) or subcutaneous prostanoids, or clinical worsening of PAH (decreased 6-minute walk distance, worsened PAH symptoms and need for additional PAH treatment). Macitentan Tablets also reduced hospitalization for PAH. It may not be indicated for certain other uses due to unexpired exclusivities for the RLD for such uses.

Macitentan Tablets, 10 mg have an estimated market size of US\$ 797 million for twelve months ending Dec 2021 according to IQVIA.

Alembic has received year to date (YTD) 22 approvals (15 final approvals and 7 tentative approvals) and a cumulative total of 161 ANDA approvals (138 final approvals and 23 tentative approvals) from USFDA.

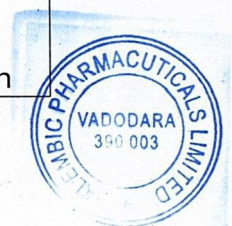
**About Alembic Pharmaceuticals Limited**

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 <https://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 - 6637630
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, INDIA • TEL : +91-265-2280550 • FAX : +91-265-2282837  
Website : [www.alembicpharmaceuticals.com](http://www.alembicpharmaceuticals.com) • E-mail : [alembic@alembic.co.in](mailto:alembic@alembic.co.in)  
CIN : L24230GJ2010PLC061123