

Date: 8th December, 2021

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Tower, Dalal Street,
Fort, Mumbai – 400 001

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals Limited receives USFDA Tentative Approval for Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg, and 1,600 mcg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Tentative Approval for Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg, and 1,600 mcg.

Please find enclosed herewith our press release.

We request you to kindly take the same on record.

Thanking you,

Yours faithfully,
For Alembic Pharmaceuticals Limited


Charandeep Singh Saluja
Company Secretary

Encl.: A/a.

ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE : ALEMBIC ROAD, VADODARA - 390 003. • TEL : (0265) 2280550, 2280880 • FAX : (0265) 2281229
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PRESS RELEASE

8th December, 2021, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg, and 1,600 mcg.

Alembic Pharmaceuticals Limited (Alembic) today announced that the Company has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg, and 1,600 mcg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Upravi Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg, and 1,600 mcg, of Actelion Pharmaceuticals, Ltd. (Actelion). Selexipag Tablets are indicated for the treatment of pulmonary arterial hypertension (PAH) to delay disease progression and reduce the risk of hospitalization for PAH.

Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg, and 1,600 mcg have an estimated market size of US\$ 461 million for twelve months ending September 2021 according to IQVIA.

Alembic has received year to date (YTD) 15 approvals (11 final approvals and 4 tentative approvals) and a cumulative total of 154 ANDA approvals (134 final approvals and 20 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)

For more information contact:

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