Date: 12th July, 2024

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001
BSE Scrip Code: 533573

To,
The Manager,
Listing Department,
National Stock Exchange of India Ltd.
'Exchange Plaza', Bandra Kurla
Complex, Bandra (E), Mumbai – 400 051
NSE Symbol: APLLTD

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Tentative Approval for Selexipag for Injection, 1,800 mcg/vial.

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 for Injection, 1,800 mcg/vial.

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

Manisha Saraf Digitally signed by Manisha Saraf
Date: 2024.07.12 16:35:28 +05'30'

Manisha Saraf
Company Secretary

Encl.: A/a.

PRESS RELEASE

12th July, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Tentative Approval for Selexipag for Injection, 1,800 mcg/vial.

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) Selexipag for Injection, 1,800 mcg/vial. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Uptravi® for Injection, 1,800 mcg/vial, of Actelion Pharmaceuticals US, Inc. (Actelion). Selexipag is a prostacyclin receptor agonist indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. Refer label for a detailed indication.

Based on the most recent update to the FDA's online paragraph IV database listings[1], Alembic is the sole first applicant to have filed its ANDA for Selexipag for Injection, 1,800 mcg/vial, containing a Paragraph IV certification under the provisions of the Hatch-Waxman Act. Upon final approval of this ANDA by USFDA, Alembic may be eligible for 180 days of generic marketing exclusivity in the U.S.

Alembic has a cumulative total of 208 ANDA approvals (180 final approvals and 28 tentative approvals) from USFDA.

[1]See FDA's list of drug products for which an ANDA has been received by the Office of Generic Drugs containing a "Paragraph IV" patent certification.(https://www.fda.gov/media/166048/download?attachment)

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

Phone: +91 22-66953681| 7045504460
Email: ajay.desai@alembic.co.in

ALEMBIC PHARMACEUTICALS LIMITED VADODARA 390 003

Safe Harbor Statement
Uptravi® is a registered trademark of Actelion Pharmaceuticals and/or its affiliates.