Date: 17th June, 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 Final Approval for Icatibant Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Final Approval for Icatibant Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe. This is the first peptide product approval from the USFDA received by the Company.

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: 2024.06.17 12:02:05 +05'30'

Manisha Saraf
Company Secretary

Encl.: A/a.

PRESS RELEASE

17th June, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Icatibant Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Icatibant Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Firazyr Injection, 30 mg/3 mL (10 mg/mL), of Takeda Pharmaceuticals U.S.A., Inc. Icatibant injection is indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older. Refer label for a detailed indication.

This is the first peptide product approval from the USFDA received by the Company.

Icatibant Injection has an estimated market size of US$ 112 million for twelve months ending Mar 2024 according to IQVIA.

Alembic has a cumulative total of 205 ANDA approvals (177 final approvals and 28 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:

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