Date: 24th May, 2022

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

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Pirfenidone Tablets, 267 mg and 801 mg.

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 Pirfenidone Tablets, 267 mg and 801 mg.

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.

PRESS RELEASE

24th May, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Pirfenidone Tablets, 267 mg and 801 mg.

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 Pirfenidone Tablets, 267 mg and 801 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Esbriet Tablets, 267 mg and 801 mg, of Genentech, Inc. (Genentech). Pirfenidone Tablets are indicated for the treatment of idiopathic pulmonary fibrosis (IPF). Alembic had previously received tentative approval for this ANDA. Alembic was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification. It may not be indicated for certain other uses due to unexpired exclusivities for the RLD for such uses.

Pirfenidone Tablets, 267 mg and 801 mg have an estimated market size of US$ 548 million for twelve months ending December 2021 according to IQVIA. Alembic has settled the case with Genetech and will launch its generic as per the terms of settlement.

Alembic has a cumulative total of 167 ANDA approvals (144 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:

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