Date: 22nd December, 2022

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

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 announces its first product approval from its Formulation Division IV, Jarod Facility.

With reference to the captioned subject, this is to inform the exchange that the Company has received PAS (Prior Approval Supplement) approval from US Food & Drug Administration (USFDA) for Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 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

Digitally signed by CHARANDEEP SINGH SALUJA
DN: c=IN, o=Personal, pseudonym=a60bda6662cacaa6dee424354752c8af217d06e3e0b6cc73c4bb1acdf09b43c5, postalCode=390008, st=GUJARAT, serialNumber=2df2425a9d726770b9617 8ea7d183d3b13c8557e9c4be4aaf90236628eb533e7, cn=CHARANDEEP SINGH SALUJA
Date: 2022.12.22 13:46:09 +05'30'

Charandeep Singh Saluja
Company Secretary

Encl.: A/a.

PRESS RELEASE

22nd December, 2022, Vadodara, India

Alembic Pharmaceuticals announces its first product approval from its Formulation Division IV, Jarod Facility.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received PAS (Prior Approval Supplement) approval from the US Food & Drug Administration (USFDA) for its Supplemental Abbreviated New Drug Application (sANDA) Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg.

The sANDA, submitted as “Prior Approval Supplement," provides for an alternate drug product manufacturing site - Alembic Pharmaceuticals Limited, Formulation Division IV, Jarod, Gujarat, India for previously approved ANDA from Panelav Facility (F-I). This is the first product approval from Jarod Facility which was inspected in Dec 2022.

The approved sANDA is therapeutically equivalent to the reference listed drug product (RLD), Lyrica Capsules, of Upjohn. Pregabalin Capsules are indicated for neuropathic pain, postherpetic neuralgia, and other indications. Refer to our label for full indication.

Pregabalin Capsules have an estimated market size of US$ 244 million for twelve months ending Sep 2022 according to IQVIA.

Alembic has a cumulative total of 178 ANDA approvals (155 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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