Date: 1st March, 2023

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 receives USFDA Final Approval for Docetaxel Injection USP, 20 mg/2 mL (10 mg/mL) Single-Dose Vial, and 80 mg/8 mL (10 mg/mL) and 160 mg/16 mL (10 mg/mL) Multiple-Dose Vials.

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 Docetaxel Injection USP, 20 mg/2 mL (10 mg/mL) Single-Dose Vial, and 80 mg/8 mL (10 mg/mL) and 160 mg/16 mL (10 mg/mL) Multiple-Dose Vials.

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
Date: 2023.03.01 11:11:25 +05'30'

Charandeep Singh Saluja
Company Secretary
Encl.: A/a.

PRESS RELEASE

1st March, 2023, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Docetaxel Injection USP, 20 mg/2 mL (10 mg/mL) Single-Dose Vial, and 80 mg/8 mL (10 mg/mL) and 160 mg/16 mL (10 mg/mL) Multiple-Dose Vials.

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) Docetaxel Injection USP, 20 mg/2 mL (10 mg/mL) Single-Dose Vial, and 80 mg/8 mL (10 mg/mL) and 160 mg/16 mL (10 mg/mL) Multiple-Dose Vials. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Docetaxel Injection, 20 mg/2 mL, 80 mg/8 mL, and 160 mg/16 mL (10 mg/mL), of Hospira, Inc. Docetaxcel Injections are indicated for the breast cancer, non-small cell lung cancer, castration-resistant prostate cancer, gastric adenocarcinoma and squamous cell carcinoma of head and neck. Refer to our label for full indication.

Docetaxel Injection USP, 20 mg/2 mL (10 mg/mL) Single-Dose Vial, and 80 mg/8 mL (10 mg/mL) and 160 mg/16 mL (10 mg/mL) Multiple-Dose Vials, have an estimated market size of US$ 11 million for twelve months ending Dec 2022 according to IQVIA.

Alembic has a cumulative total of 181 ANDA approvals (158 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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ALEMBIC PHARMACEUTICALS LIMITED VADODARA 390 003