Alembic
Touching Lives over 100 years

Date: 27th October, 2022

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

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Paclitaxel Injection USP, 30 mg/5 mL (6 mg/mL), 100 mg/16.7 mL (6 mg/mL), and 300 mg/50 mL (6 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 Paclitaxel Injection USP, 30 mg/5 mL (6 mg/mL), 100 mg/16.7 mL (6 mg/mL), and 300 mg/50 mL (6 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
DN: c=IN, o=Personal,
pseudonym=a60bda6662cacaa6dee424354752c8af217d06e3e0b6cc73c4bb1acdf09b43c5, postalCode=390008, st=GUJARAT,
serialNumber=2df2425a9d726770b96178ea7d183d3b13c8557e9c4be4aaf90236628eb533e7, cn=CHARANDEEP SINGH SALUJA
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Charandeep Singh Saluja
Company Secretary

Encl.: A/a.

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PRESS RELEASE

27th October, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Paclitaxel Injection USP, 30 mg/5 mL (6 mg/mL), 100 mg/16.7 mL (6 mg/mL), and 300 mg/50 mL (6 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) for Paclitaxel Injection USP, 30 mg/5 mL (6 mg/mL), 100 mg/16.7 mL (6 mg/mL), and 300 mg/50 mL (6 mg/mL) Multiple-Dose Vials.

This is the first product approval for oncology injection from our F-2 Facility (Oncology Injectable) which recently completed the first USFDA inspection.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Taxol Injection, 30 mg/5 mL (6 mg/mL), 100 mg/16.7 mL (6 mg/mL), and 300 mg/50 mL (6 mg/mL). Paclitaxel Injection, USP is indicated i) as subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, Paclitaxel Injection, USP is indicated in combination with cisplatin. ii) for the adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin containing combination chemotherapy. In the clinical trial, there was an overall favorable effect on disease-free and overall survival in the total population of patients with receptor-positive and receptor-negative tumors, but the benefit has been specifically demonstrated by available data (median follow-up 30 months) only in the patients with estrogen and progesterone receptor negative tumors. iii) for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. iv) in combination with cisplatin, is indicated for the first-line treatment of non small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy. v) for the second-line treatment of AIDS-related Kaposi's sarcoma.

Paclitaxel Injection USP, has an estimated market size of US$ 26 million for twelve months ending June 2022 according to IQVIA.

Alembic has a cumulative total of 172 ANDA approvals (148 final approvals and 24 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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