

Date: 26<sup>th</sup> 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 receives USFDA Final Approval for Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) per 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 Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) per Single-Dose Prefilled Syringe.

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.

**ALEMBIC PHARMACEUTICALS LIMITED**

**PRESS RELEASE**

26<sup>th</sup> December, 2022, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Final Approval for Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) per 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), Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) per Single-Dose Prefilled Syringe. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Faslodex Injection, 250 mg/5 mL (50 mg/mL), of AstraZeneca Pharmaceuticals LP. Fulvestrant Injection is an estrogen receptor antagonist indicated for the treatment of breast cancer. Refer to our label for full indication.

Fulvestrant Injection, 250 mg/5 mL, has an estimated market size of US\$71 million for twelve months ending Sep 2022 according to IQVIA.

Alembic has received a cumulative total of 179 ANDA approvals (156 final approvals and 23 tentative approvals) from USFDA.

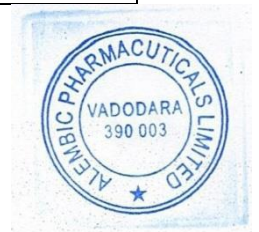
**About Alembic Pharmaceuticals Limited**

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**

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