

Date: 22<sup>nd</sup> November, 2019

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 Approvals

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Approval for its following Abbreviated New Drug Applications (ANDAs):

- 1. Final Approval for Deferasirox Tablets 90 mg and 360 mg.
- 2. Final Approval for Deferasirox Tablets for Oral Suspension, 125 mg, 250 mg, and 500 mg.
- 3. Tentative Approval for Deferasirox Tablets 180 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.



MACU

VADODARA

## **PRESS RELEASE**

22<sup>nd</sup> November, 2019, Vadodara, India

## Alembic Pharmaceuticals receives USFDA Approvals

Alembic Pharmaceuticals Limited today announced that the Company has received approval from US Food & Drug Administration (USFDA) for its following Abbreviated New Drug Applications (ANDAs):

USFDA	Name of	Dosage	Equivalent to	Usage	Estimated
Approval	the ANDAs		reference listed drug product (RLD)		Market Size
Final	Deferasirox Tablets	90 mg and 360 mg	Jadenu Tablets, 90 mg and 360 mg, of Novartis Pharmaceuticals Corporation (Novartis).	Treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older.	US\$ 415 million for twelve months ending December 2018 according to IQVIA.
Final	Deferasirox Tablets for Oral Suspension	125 mg, 250 mg, and 500 mg	Exjade Tablets for Oral Suspension, 125 mg, 250 mg, and 500 mg, of Novartis Pharmaceuticals Corporation (Novartis).	Same as above.	US\$ 135 million for twelve months ending December 2018 according to IQVIA.
Tentative	Deferasirox Tablets	180 mg	Jadenu Tablets, 180 mg, of Novartis Pharmaceuticals Corporation (Novartis).	Same as above.	US\$59 million for twelve months ending December 2018 according to IQVIA.

Alembic now has a total of 107 ANDA approvals (95 final approvals and 12 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 the company can be found at http://www.alembicpharmaceuticals.com/; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573).

For more information contact:

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