Alembic
Touching Lives over 100 years

Date: 22nd April, 2019

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 two ANDA approvals from USFDA

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

1. Teriflunomide Tablets, 7 mg and 14 mg
2. Tobramycin Ophthalmic Solution USP, 0.3%

Please find enclosed herewith our press releases for both the products separately.

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.

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PRESS RELEASE

22nd April, 2019, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Teriflunomide Tablets, 7 mg and 14 mg.

Alembic Pharmaceuticals Limited today announced that the company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Teriflunomide Tablets, 7 mg and 14 mg. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Aubagio Tablets, 7 mg and 14 mg, of Sanofi-Aventis U.S., LLC (Sanofi-Aventis). Teriflunomide tablets are indicated for the treatment of patients with relapsing forms of multiple sclerosis.

Teriflunomide Tablets, 7 mg and 14 mg have an estimated market size of US$ 1.6 billion for twelve months ending December 2018 according to IQVIA. Alembic has settled the litigation and will launch the product as per the terms of the settlement.

Alembic now has a total of 91 ANDA approvals (79 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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ALEMBIC PHARMACUTICALS LIMITED VADODARA 390 003

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PRESS RELEASE

22nd April, 2019, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Tobramycin Ophthalmic Solution USP, 0.3%.

Alembic Pharmaceuticals Limited today announced that the company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Tobramycin Ophthalmic Solution USP, 0.3%. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Tobrex Ophthalmic Solution, 0.3%, of Novartis Pharmaceuticals Corporation. Tobramycin Ophthalmic Solution USP, 0.3% is a topical antibiotic indicated in the treatment of external infections of the eye and its adnexa caused by susceptible bacteria.

Tobramycin Ophthalmic Solution USP, 0.3% have an estimated market size of US$ 9.6 million for twelve months ending December 2018 according to IQVIA.

Alembic now has a total of 92 ANDA approvals (80 final approvals and 12 tentative approvals) from USFDA.

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