Date: 11th June, 2026

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001
BSE Scrip Code: 533573

To,
The Manager,
Listing Department,
National Stock Exchange of India Ltd.
'Exchange Plaza', Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
NSE Symbol: APLLTD

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals Limited receives USFDA Tentative Approval for Larotrectinib Capsules, 25 mg and 100 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Tentative Approval for Larotrectinib Capsules, 25 mg and 100 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

MANISHA SARAF Digitally signed by MANISHA SARAF Date: 2026.06.11 12:19:16 +05'30'

Manisha Saraf
Company Secretary
Encl.: A/a.

PRESS RELEASE

11th June, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Tentative Approval for Larotrectinib Capsules, 25 mg and 100 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Larotrectinib Capsules, 25 mg and 100 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Vitrakvi Capsules, 25 mg and 100 mg, of Bayer Healthcare Pharmaceuticals Inc. (Bayer). Larotrectinib is a kinase inhibitor indicated for the treatment of adult and pediatric patients with solid tumors that: a) have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, b) are metastatic or where surgical resection is likely to result in severe morbidity, and c) have no satisfactory alternative treatments or that have progressed following treatment. Refer label for a detailed indication.

Based on the most recent update to the FDA's online Paragraph IV database listings, Alembic is the sole first applicant to have filed its ANDA for Larotrectinib Capsules (25 mg and 100 mg), containing a Paragraph IV certification under the provisions of the Hatch-Waxman Act. Upon final approval of this ANDA by the USFDA, Alembic may be eligible for 180 days of generic marketing exclusivity in the U.S.

Larotrectinib Capsules, 25 mg and 100 mg, have an estimated market size of US$ 91 million for twelve months ending March 2026 according to IQVIA.

Alembic has a cumulative total of 241 ANDA approvals (221 final approvals and 20 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 field force of over 5500 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

For more information, contact:
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