

PRESS RELEASE

14th May, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Tentative Approval for Darolutamide Tablets, 300 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) Darolutamide Tablets, 300 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Nubeqa Tablets, 300 mg, of Bayer HealthCare Pharmaceuticals Inc. (Bayer). Darolutamide is an androgen receptor inhibitor indicated for the treatment of adult patients with: i) non-metastatic castration-resistant prostate cancer (nmCRPC), ii) metastatic castration-sensitive prostate cancer (mCSPC), and iii) metastatic castration-sensitive prostate cancer (mCSPC) in combination with docetaxel. Refer label for a detailed indication.

Darolutamide Tablets, 300 mg, have an estimated market size of US\$ 3,155 million for twelve months ending March 2026 according to IQVIA.

Alembic has a cumulative total of 238 ANDA approvals (219 final approvals and 19 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:

Ajay Kumar Desai

Phone: +91 22-66953681

Email: ajay.desai@alembic.co.in



ALEMBIC PHARMACEUTICALS LIMITED