

**PRESS RELEASE**

9<sup>th</sup> March, 2023, Vadodara, India

**Alembic Pharmaceuticals announces USFDA Tentative Approval for Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 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) Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Rexulti Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg, of Otsuka Pharmaceutical Co., Limited (Otsuka). Brexpiprazole Tablets are indicated as an adjunctive therapy to antidepressants for the treatment of major depressive disorder and for treatment of schizophrenia. It may not be indicated for certain other uses due to unexpired exclusivities for the RLD for such uses. Refer to our label for full indication.

Brexpiprazole Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg have an estimated market size of US\$ 1.6 billion for twelve months ending Dec 2022 according to IQVIA.

Alembic has a cumulative total of 184 ANDA approvals (160 final approvals and 24 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)

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