PRESS RELEASE

3rd December, 2020, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Metolazone Tablets USP 2.5 mg, 5 mg, and 10 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced it has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Metolazone Tablets USP 2.5 mg, 5 mg, and 10 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Zaroxolyn Tablets 2.5 mg, 5 mg, and 10 mg, of Lannett Company, Inc. Metolazone Tablets are indicated for the treatment of salt and water retention including: a) edema accompanying congestive heart failure; b) edema accompanying renal diseases, including the nephrotic syndrome and states of diminished renal function. Metolazone Tablets are also indicated for the treatment of hypertension, alone or in combination with other antihypertensive drugs of a different class.

Metolazone Tablets USP 2.5 mg, 5 mg, and 10 mg have an estimated market size of US$ 33 million for twelve months ending September 2020 according to IQVIA.

Alembic has a cumulative total of 137 ANDA approvals (118 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 marketing team of over 5000 are well recognized by doctors and patients.

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

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