Alembic Pharma Gets USFDA Final Approval for Generic Valganciclovir Oral Solution



New Delhi: Alembic Pharmaceuticals Limited (Alembic) has announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Valganciclovir for Oral Solution, 50 mg/mL.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Valcyte for Oral Solution 50 mg/mL of CHEPLAPHARM Arzneimittel GmbH (CHEPLAPHARM). Valganciclovir for oral solution is indicated for: 1) treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS), and 2) prevention of CMV disease in kidney, heart, or kidney-pancreas transplant patients at high risk. Refer label for a detailed indication and usage.

Alembic has a cumulative total of 247 ANDA approvals (227 final approvals and 20 tentative approvals) from the USFDA.

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.

News Source:

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