

Zydus Cadilla gets USFDA nod to market generic HIV treatment tablets

16 November 2018 | News

The company also said in the regulatory filing that it had received final approval from the United States Food and Drug Administration (USFDA) to market generic Fondaparinux Sodium injection.



Drug firm Zydus Cadila has said that it has received final approval from the US health regulator to market generic Abacavir and Lamivudine tablets used for treatment of a type of HIV infection.

The company also said in the regulatory filing that it had received final approval from the United States Food and Drug Administration (USFDA) to market generic Fondaparinux Sodium injection.

The approval from the USFDA is for Abacavir and Lamivudine tablets USP in the strength of 600 mg/300 mg, Zydus Cadila said.

The tablets are used with other antiretroviral medicines to treat human immunodeficiency virus-type 1 (HIV-1) infection that causes acquired immune deficiency syndrome (AIDS), it added.

"The product will be manufactured at the group's formulations manufacturing facility at special economic zone (SEZ), Ahmedabad," Zydus Cadila said.

The nod for the Fondaparinux Sodium injection USP is in the strengths of 2.5 mg/0.5 mL, 5 mg/0.4 mL, 7.5 mg/0.6 mL and 10 mg/0.8 mL single-dose, it added.

Fondaparinux Injection is used to treat blood clots in deep veins and the lungs. It can also be used to prevent blood clots in patients undergoing certain types of surgeries, Zydus Cadila said.

"It will be manufactured at a partner's manufacturing site," it added.

Zydus Cadila said that the group now has more than 230 approvals and has so far filed over 330 abbreviated new drug

applications (ANDAs) since the commencement of its filing process, reported PTI.	