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Glenmark US partner Salix gets FDA nod for Crofelemer tablet

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DRUG firm Glenmark Pharmaceuticals on Tuesday said US health regulator has granted marketing approval to its US partner Salix Pharmaceuticals for Crofelemer tablets used for treating diarrhoea in HIV patients.

US food and drug administration (USFDA) has provided marketing approval to its partner in US, Salix Pharmaceuticals, for Crofelemer 125 mg delayed-release tablets.

This is used for the symptomatic relief of non-infectious diarrhoea in patients with human immunodeficiency virus (HIV)/ acquired immune deficiency syndrome (AIDS) on anti-retroviral therapy, the company said.

Commenting on the development, Glenmark's CMD Glenn Saldanha said: "The USFDA approval of Crofelemer for HIV associated diarrhoea will pave the wave to launch Crofelemer across our territories. This is a significant approval milestone and will enable the first NCE launch by Glenmark across emerging markets."

Booster dose

- USFDA has given marketing given to Salix Pharmaceuticals for Crofelemer tablets
- This is used for the relief of non-infectious diarrhoea in patients with HIV/AIDS
- This is a significant step in addressing the unmet medical need of people with HIV/AIDS

Most importantly, this is a significant step forward in addressing the unmet medical need of people with HIV/AIDS on anti-retroviral therapy (ART) who experience non-infectious diarrhoea, which often can lead to reduced treatment compliance, he added.

"Crofelemer, a locally-acting, minimally-absorbed drug is believed to act by blocking chloride secretion and thus reducing the accompanying high volume water loss seen in HIV associated diarrhea...," Saldanha said. Glenmark is the sole API supplier globally for Crofelemer (ex-China), the company said.

In addition, the phase III study showed that Crofelemer did not influence the efficacy or safety of the patients HIV medications, it added. The FDA approval of Crofelemer is based on "randomised, double-blind, placebo-controlled (one month) and placebo-free (five month) multi-centre study of 374 HIV-positive patients on ART, with a history of diarrhoea for one month or more," company said.

Regulatory,