Glenmark
A new way for a new world

September 06, 2012

The Manager
Listing Dept,
The National Stock Exchange of India Ltd
Plot No. C/1,G Block
Bandra Kurla Complex
Bandra (E) Mumbai-400051

Dear Sir,

We are enclosing herewith a press release informing **"USFDA CONTINUES REVIEW OF CROFELEMER NEW DRUG APPLICATION BEYOND PDUFA GOAL DATE OF SEPTEMBER 5, 2012"** for your information and record.

Thanking you,

Yours faithfully,
For Glenmark Pharmaceuticals Ltd.

Sanjay Chowdhary
Jt. Company Secretary &Compliance officer

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Encl: As above

FDA Action on Crofelemer NDA Anticipated by End of 1Q-CY2013

Mumbai September 6, 2012 – Glenmark's collaborative partner, Salix Pharmaceuticals, Ltd, today announced that the Food and Drug Administration has advised the Company that the New Drug Application (NDA) for Crofelemer 125 mg tablets, indicated for symptomatic relief of non-infectious diarrhea in patients with HIV/AIDS on anti-retroviral therapy, is still under review and that a final action will not be taken by the scheduled Prescription Drug User Fee Act (PDUFA) goal date of September 5, 2012. Glenmark has exclusive rights for Crofelemer in Diarrhoea indications in nearly 140 countries including India and is the sole API supplier globally for Crofelemer (ex-China)

Salix, stated in its note, "The FDA continues to work collaboratively with Salix to progress this important product through its full review. By taking no action at this time, the FDA has allowed for the currently ongoing dialogue between Salix and the FDA to continue. The continuing dialogue should allow further collaboration between Salix and the Agency, a collaboration that has resulted in substantial progress in handling topics important to crofelemer and botanical products in general. The primary topic is the production and control of the crofelemer active pharmaceutical ingredient, a complex mixture that is the first botanical product to be reviewed by the Agency for oral use. This focus is needed to ensure compliance with the manufacturing and product quality requirements of the Food, Drug & Cosmetic Act. Both Salix and FDA are committed to a robust level of cooperation and data exchange with the goal of providing crofelemer to patients suffering from HIV." Crofelemer's mechanism of action is through inhibition of both cystic fibrosis transmembrane conductance regulator protein (CFTR) chloride ion channel and the calcium-activated chloride ion channels (CaCC). Crofelemer acts by blocking chloride ion channel secretion and accompanying high volume water loss in diarrhea, normalizing the flow of chloride ions and water in the GI tract. Glenmark Pharmaceuticals has exclusive rights to distribute and commercialise Crofelemer in 140 emerging countries (rest of world, or "ROW" territories) including India for indications related to HIV, use in acute adult and pediatric diarrhoea. Further Glenmark has also commenced Pivotal trials for Adult Acute Diarrhoea including Cholera in India and Bangladesh

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