glenmark
A new way for a new world

January 2, 2013

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 APPROVES CROFELEMER 125 MG DELAYED-RELEASE TABLETS FOR THE SYMPTOMATIC RELIEF OF DIARRHEA IN PATIENTS WITH HIV/AIDS ON ANTI-RETROVIRAL THERAPY (ART). This will be the first NCE(New Chemical Entity) launch by an Indian company across multiple geographies**" for your information and record.

Thanking you,

Yours faithfully,
For Glenmark Pharmaceuticals Ltd.

Sanjay Chowdhary
Jt. Company Secretary & Compliance Officer

Tel: 4018 9999 / 4018 9879
Fax No: 4018 9986 (Legal & Secretarial Dept.)

Encl: As above

Press Release **For Immediate Dissemination**

USFDA APPROVES CROFELEMER 125 MG DELAYED-RELEASE TABLETS FOR THE SYMPTOMATIC RELIEF OF DIARRHEA IN PATIENTS WITH HIV/AIDS ON ANTI-RETROVIRAL THERAPY (ART)

- Glenmark has exclusive Crofelemer rights for diarrhea indications in 140 countries including India and the approval will accelerate filing and launch preparations across its territories.
- **This will be the first NCE(New Chemical Entity) launch by an Indian company across multiple geographies**
- Glenmark is the sole API supplier globally for Crofelemer (ex-China)

Mumbai, India, January 2, 2013 - Glenmark Pharmaceuticals Limited announced today that the US Food and Drug Administration has provided Marketing approval to its partner in US, Salix Pharmaceuticals Limited for Crofelemer 125 mg delayed-release tablets for the symptomatic relief of non-infectious diarrhea in patients with human immunodeficiency virus (HIV)/ acquired immune deficiency syndrome (AIDS) on anti-retroviral therapy (ART)

"The USFDA approval of Crofelemer for HIV associated diarrhea 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. Most importantly, this is a significant step forward in addressing the unmet medical need of people with HIV/AIDS on ART who experience non-infectious diarrhea, which often can lead to reduced treatment compliance. This will also help us accelerate filing across countries and also propel our development in additional diarrhea indications including the acute indications," **said Glenn Saldanha, Chairman & MD, Glenmark Pharmaceuticals Limited.** 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. It is this secretion that is believed to lead to diarrhea with the associated symptoms of dehydration, electrolyte imbalance, abdominal cramping, urgency and increased frequency.

Crofelemer is believed to improve HIV associated diarrhea via dual mechanisms of action with inhibition of both CFTR (Cystic Fibrosis Transmembrane Conductance Regulator Protein) and CaCC (calcium-activated chloride channel) resulting in reduced chloride ion secretion into the GI lumen[2]

Data supports the use of Crofelemer as an orally administered, anti-secretory anti-diarrheal agent that may provide relief to patients through the inhibition of chloride secretion into the gut. In addition, the Phase 3 study showed that Crofelemer did not influence the efficacy or safety of the patients HIV medications. The FDA approval of Crofelemer is based on a randomized, double-blind, placebo-controlled (one month) and placebo-free (five month), multi-center study of 374 HIV-positive patients on ART, with a history of diarrhea for one month or more. The primary efficacy endpoint was the proportion of patients experiencing less than or equal to two watery bowel movements per week, during at least two of the four weeks of the placebo-controlled phase of the study. Patients who received concomitant anti-diarrheal medications or opiates were counted as clinical non-responders.

Data demonstrated that a significantly larger proportion of patients taking Crofelemer 125 mg twice daily experienced clinical response compared with patients in the placebo group. In addition, statistically significant reductions from baseline to the end of the double-blind period also were observed for the number of watery bowel movements per day, and daily stool consistency score, among patients taking Crofelemer compared with placebo. Further, the Crofelemer treatment effect for clinical response (125 mg twice daily vs. placebo) was similar in subgroup analyses based on duration of diarrhea, baseline number of daily watery bowel movements, use of protease inhibitors (PI), and CD4 cell count. The most common adverse reactions in the study were respiratory tract infection, bronchitis, cough, flatulence, and increased bilirubin.

Important Safety Information for Crofelemer

In clinical studies, the most common adverse reactions (occurring in ≥ 3% patients and at a rate greater than placebo) were upper respiratory tract infection, bronchitis, cough, flatulence and increased bilirubin.

About Crofelemer

Crofelemer is a first-in-class, gastrointestinal agent derived on a sustainable basis from the *Croton lechleri* plant, native to northwestern South America. Crofelemer acts as an anti-secretory, anti-diarrheal agent that works locally in the GI lumen and exhibits minimal systemic absorption. At the recommended dose of one 125 mg delayed-release tablet taken orally, twice daily, Crofelemer works to inhibit both the cyclic adenosine monophosphate (cAMP)-stimulated cystic fibrosis transmembrane conductance regulator (CFTR) chloride ion (C1-) channel, and the calcium-activated C1- channels (CaCC).

Inhibiting CFTR and CaCC reduces the secretion of chloride ions, along with the water that enables their transport, out of the circulatory system and into the intestinal lumen. The secretion of chloride ions has been shown to cause diarrhea, with the associated symptoms of dehydration, electrolyte imbalance, abdominal cramping, urgency and increased frequency. Unlike other anti-diarrheal agents, Crofelemer does not appear to affect gut motility.

Glenmark obtained rights to crofelemer under license from Napo Pharmaceuticals, Inc.

About Glenmark:

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. It is ranked among the top 100 Pharma & Biotech companies of the world in terms of revenues. *(SCRIP 100 Rankings published in the year 2012)* Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain]. The company has a significant presence in branded generics markets across emerging economies including India. GPL along with its subsidiary has 13 manufacturing facilities in four countries and has five R&D centers. Its subsidiary, Glenmark Generics Limited services the requirements of the US and Western Europe generics markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India.

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