Press Release **For Immediate Dissemination**

Crofelemer, a first-in-class anti-diarrhoeal drug, successfully completes Phase III trials for HIV-associated diarrhoea

Glenmark prepares for the launch of Crofelemer in 140 countries globally and this could potentially be the first novel drug launched by the organisation

- The Phase III study for Crofelemer demonstrates highly statistically significant results in the treatment of chronic diarrhea in people living with HIV
- Pivotal phase 3 trial confirms efficacy and dose
- Glenmark has Crofelemer rights for diarrhea indications in 140 countries including India and is the sole API supplier globally for Crofelemer (ex-China)

Monday, November 8, 2010: Crofelemer, a first-in-class anti-diarrhoeal drug, successfully completes Phase III trials for HIV-related diarrhoea. The completion of top-line analysis of the primary efficacy endpoint from the Phase 3 ADVENT trial, a randomized, double-blind, parallel-group, placebo-controlled, two-stage, adaptive design to evaluate the safety and efficacy of Crofelemer in the treatment of chronic diarrhoea in people living with HIV/AIDS on anti-retroviral therapy ("ARV") was announced in the United States by Glenmark's partners Napo Pharmaceuticals and Salix Pharmaceuticals. Glenmark has exclusive marketing and distribution rights to this novel anti-diarrhoeal compound for multiple diarrhoea indications across 140 countries. Glenmark is also the sole global API supplier globally (ex China).

Crofelemer at a daily dose of 125 mg twice daily demonstrated a highly statistically significant improvement in the primary responder analysis, defined as patients having two or less watery stools in two of the four week placebo-controlled phase. Crofelemer was well tolerated in this study and its adverse event profile was not different from that of the placebo-treated group.

"The results from these pivotal Phase III studies for Crofelemer in the treatment of HIV-associated diarrhoea are very encouraging for Glenmark as this will accelerate our goal to provide patients access to this drug across multiple diarrhoeal conditions. We are encouraged by these results as we could now prepare for the launch of Crofelemer and this will be our first novel product" said **Mr. Glenn Saldanha, CEO & MD, Glenmark Pharmaceuticals Limited.**1"Besides HIV-related diarrhoea, most of the

markets where Glenmark has exclusive rights have significant incidence of acute diarrhoea especially in young children. Crofelemer has previously shown benefit in patients with mild to severe acute watery diarrhoea. Glenmark will invest significant resources to fast track its development plan to ensure early regulatory approvals and launch in most of our markets."

The ADVENT trial is being conducted under a "fast track" status and has been a part of a "special protocol assessment" ("SPA") agreement. Due to the adaptive nature of the trial design, the pre-specified p-value for the treatment difference was 0.025. The p-value achieved in the ADVENT trial was 0.0096. The aforementioned results achieve the efficacy targets set forth in the SPA agreement.

Prevalence of HIV is very high in Glenmark territories with India alone estimated to have 2.5 million people and South Africa with about 9 million people living with HIV. HIV patients manage diarrhoea on a chronic basis, which can affect adherence to life-saving anti-retroviral regimens. Crofelemer is a first-in-class, anti-secretory, anti-diarrheal agent that acts locally in the gastrointestinal tract, without significant absorption and locally regulating the fluid balance in the gut.

Glenmark Pharmaceuticals Ltd. has the exclusive license 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. Glenmark anticipates approval of Crofelemer in India in 2012. Besides Glenmark and Salix have entered into a commercial supply agreement for Crofelemer's active pharmaceutical ingredient (API).

Crofelemer is a novel, first-in-class anti-diarrheal agent that has a physiological and different mechanism of action from traditional anti-diarrheal agents. Besides its potential efficacious role in multiple diarrhoeal indications, Crofelemer controls diarrhea with no drug-drug interactions, no systemic adsorption and, unlike current anti-diarrheals, no serious side effects, and that can be used chronically.

About Glenmark Pharmaceuticals Ltd

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. It is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has eight 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 twelve manufacturing facilities in four countries and has five R&D centres.

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