



Glenmark Generics Limited

---

Press Release

For Immediate Release

## **Glenmark to market Levetiracetam tablets for the US market. U.S. FDA grants Day 1 ANDA approval**

- Levetiracetam tablets are indicated as an adjunctive therapy for the treatment of partial onset seizures in adults and children with epilepsy
- Estimated market size for Levetiracetam tablets is around USD 1.1 billion\*

**January 16, 2009:** Glenmark Generics Inc., USA (GGI), the subsidiary of Glenmark Generics Limited (GGL), has today commenced marketing and distribution of Levetiracetam 250 mg, 500 mg and 750 mg tablets in the U.S. market.

Levetiracetam tablets are indicated as an adjunctive therapy for the treatment of partial onset seizures in adults and children (above 4 years) with epilepsy. \*According to IMS Health data for the 12 month period ending September 2008, Levetiracetam tablets recorded sales of USD 1.1 Billion, growing at a rate of 36% over the corresponding period for the previous year. For the 12 month period ending September 2008, Levetiracetam is ranked within the top 5 oral solid anti-epileptic (N3A) products.

Glenmark initiated shipping immediately upon final ANDA approval for Levetiracetam tablets from the U.S. FDA through its longstanding partnership with Invagen Pharmaceuticals Inc. Based on the terms of this collaboration Glenmark will exclusively market and distribute the product while Invagen will be responsible for the manufacture and supply. With this launch, Glenmark will now have 38 generic products authorized for distribution in the US market.

**Terrance Coughlin, Chief Executive Officer, Glenmark Generics Limited stated,** "This day 1 approval has tremendous significance for Glenmark as we would be one of the first few companies to launch the generic version of UCB Inc's product Keppra® and we have already commenced distribution." **He further commented,** "From the beginning we have focused on building a diversified pipeline which would enable us grow at a faster rate. Also, to remain competitive in this market it is imperative to execute a mix of launch strategies - and this day one launch of Levetiracetam is another indication of our strong operational capabilities to begin distribution as soon as we received the



## Glenmark Generics Limited

---

approval. We are confident that this product will be very successful in the marketplace.”

The US subsidiary currently has over 40 ANDAs filed with the U.S. FDA pending approval. In addition to these internal filings, GGI continues to identify and explore external development partnerships to supplement and accelerate the growth of the existing pipeline and portfolio.

### **About Glenmark Generics Ltd.:**

Glenmark Generics Limited (GGL) is a subsidiary of Glenmark Pharmaceuticas Limited (Glenmark) and aims to be a global integrated Generic and API leader. GGL has an established presence in North America, EU and Argentina and maintains marketing front-ends in these countries. GGL has a strong base in Formulations development with teams operating out of laboratories in India and Latin America. The Company has a state-of-the-art manufacturing plant at Goa, India that is approved by US FDA, TPD (Canada), MHRA, UK and many other overseas regulatory authorities. GGL also markets over 45 APIs to more than 80 countries across the world and had over 30 USDMFs filed and/or approved along with several Canadian DMFs, EDMFs and CEPs/CoSs. [[www.glenmark-generics.com](http://www.glenmark-generics.com)]

### **About Glenmark Pharmaceuticals Ltd.:**

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. The company is listed on India's two premier stock exchanges, the Bombay Stock Exchange (BSE) and the National Stock Exchange (NSE). It employs over 5500 people across its global operations over 85 countries. The Company is a leader in India in the discovery of new molecules and is focused in the areas of inflammation [Asthma/COPD, etc.], and metabolic disorders [Diabetes, Obesity, etc.]. The Company is in the process of creating marketing front-ends for the launch of its proprietary products in the future. Glenmark's first Asthma/COPD molecule, Oglemilast [GRC 3886], was licensed out to Forest Laboratories and Teijin Pharma Limited for the North American and Japanese markets, respectively, in two landmark deals. Oglemilast is presently undergoing Phase II clinical trials in the US. GRC 6211 has been out-licensed to Eli Lilly & company. For more information on GPL, log on to <http://www.glenmarkpharma.com/>

### ***For further information, please contact:***

Jason D'Souza | Medha Satam

Glenmark, Mumbai, India

Tel: [+91 22] 40189919 / 40189993 Email : [connect@glenmark-generics.com](mailto:connect@glenmark-generics.com)