

Press Release

For Immediate Release

## **Glenmark launches Nabumetone and Hydroxyzine Hydrochloride Tablets**

**Mumbai, March 13, 2008:** Glenmark Pharmaceuticals Inc (GPI), the US subsidiary of Glenmark Pharmaceuticals Limited (Glenmark), one of the world's leading, integrated specialty pharmaceutical and high-quality generic companies, has initiated the marketing and distribution of Nabumetone tablets and Hydroxyzine Hydrochloride tablets in the U.S. market.

Glenmark commenced shipping immediately upon final approval from the U.S. Food and Drug Administration for an Abbreviated New Drug Application (ANDA) for: Nabumetone tablets in 500mg and 750mg strengths and Hydroxyzine Hydrochloride tablets in 10mg, 25mg and 50mg strengths, through its partnership with InvaGen Pharmaceuticals Inc (InvaGen).

The Company will exclusively market and distribute Nabumetone and Hydroxyzine Hydrochloride tablets while InvaGen will be responsible for their manufacture and supply. All development, regulatory costs and profits on Nabumetone and Hydroxyzine Hydrochloride tablets' sale in the US will be shared equally between Glenmark and InvaGen.

Nabumetone is a non-steroidal anti-inflammatory drug and is used to treat pain or inflammation caused by arthritis. According to IMS Health data, for the 12 month period ending December 2007, the market size of Nabumetone was USD 97 million.

Hydroxyzine belongs to a group of medicines called sedating antihistamines. Its main use is to help in the treatment of anxiety. According to IMS Health data, for the 12 month period ending December 2007, the market size of Hydroxyzine Hydrochloride was USD 60 million.

In FY 06, Glenmark and InvaGen entered into a collaboration agreement for the joint development, filing and marketing of seven generic pharmaceutical products for the US market. The product list included a mixture of off-patent and patent-protected molecules with cumulative annual sales in the US of about USD 4.1 billion.

This recent approval expands Glenmark's portfolio to 28 generic products for the US market. The Company has over 35 ANDAs undergoing review with the US FDA for approval/launch.

### **About Glenmark Pharmaceuticals Inc., USA [GPI]**

Glenmark's US subsidiary, Glenmark Pharmaceuticals Inc., USA [GPI], was established in 2003 to enter into the world's largest pharmaceutical market. GPI is responsible for sales and marketing of generic drug formulations in the USA as well as APIs to customers in the regulated markets. GPI closed last Fiscal year with sales of USD 50 Mn from its formulations business.

### **About Glenmark**

Glenmark Pharmaceuticals Ltd. is a research-led, global, fully integrated pharmaceutical company headquartered in Mumbai, India. The Company is a leader in India in the discovery of new molecules. Glenmark has 11 lead molecules at various stages of development in NCE & NBE research. Three of the leads are in Phase II whereas eight other leads are into the pre-clinical and discovery stages in the broad areas of inflammation, metabolic disorders and oncology.

The Company has generic formulation and API business interests in over 80 countries across the world including the highly regulated markets of USA and Europe. The formulation business spans several product segments such as Dermatology, Internal Medicine, Paediatrics, Gynaecology, ENT, Cardiology, Diabetes and Oncology.

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. The second molecule, GRC 6211 (targeting pain), which is undergoing Phase II clinical trials in Europe, has recently been out-licensed to Eli Lilly & company. [www.glenmarkpharma.com](http://www.glenmarkpharma.com)

### **About Invagen**

InvaGen Pharmaceuticals, Inc. is a leading US generic pharmaceutical company based in Long Island, New York. The company is vertically integrated with a leading active pharmaceutical manufacturer based in India. InvaGen has filed 28 ANDAs till date with the USFDA. [www.invagen.com](http://www.invagen.com)

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