



Glenmark Generics Limited

Press Release

For Immediate Release

## **Glenmark Generics receives three ANDA approvals** **- Portfolio of 32 products for the US market**

**Mumbai, May 30, 2008:** Glenmark Generics Limited (GGL), a subsidiary of Glenmark Pharmaceuticals Ltd. (Glenmark), has received ANDA approvals for Mometasone Furoate Ointment USP, 0.1%, Mometasone Furoate Cream USP, 0.1% and Metformin Hydrochloride Tablets USP 500 mg, 850 mg and 1000 mg and will soon commence marketing and distribution of these products in the US market.

**Mometasone Furoate** is a medium potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Like other topical corticosteroids, Mometasone Furoate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The total sales for the two Mometasone Furoate products in the 12 month period ending March 2008 were in excess of USD 29 million, as per IMS Health.

Mometasone will be manufactured at Glenmark's Baddi facility in India. Glenmark has recently received US FDA approval for its state of the art semi-solids manufacturing plant at Baddi, Himachal Pradesh. The Baddi plant also received GMP approval from MHRA of UK, and from TPD, Canada. The US FDA approval will now enable Glenmark to enter the niche segment of semi-solid dosages in most of the regulated markets of the world. Glenmark is a leader in the dermatology segment in India with brands like Candid, Candid TV, Candiderma and has over 30 brands in the domestic market.

GGL had earlier acquired the US marketing rights for a line of Clobetasol Propionate dermatology products that include - Cream, E Cream, Ointment, Gel and Topical Solution through a US based pharmaceutical development company. The Company commenced marketing and distribution of these products in March.

**Metformin Hydrochloride** tablets as monotherapy are indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. As of 2007, it is one of only two oral anti-diabetics in the World Health Organization Model List of Essential Medicines (the other being Glibenclamide). The total sales for Metformin Hydrochloride tablets in the 12 month period ending March 2008 were in excess of USD \$158 million as per IMS Health.

Based on these recent launches, GGL now has a portfolio of 32 generic products for the US market. The Company currently has over 35 ANDAs undergoing US FDA approval process/launch.



## Glenmark Generics Limited

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### **About Glenmark Generics Ltd. (GGL)**

Glenmark Generics Limited (GGL) is a subsidiary of Glenmark Pharmaceuticals 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. GGL generated USD 196 Mn in Net Sales in FY08.

[[www.glenmark-generics.com](http://www.glenmark-generics.com)]

### **About Glenmark Pharmaceuticals Ltd. (Glenmark)**

Glenmark Pharmaceuticals Ltd. (Glenmark) is a research-driven, global, fully integrated pharmaceutical company headquartered at Mumbai, India. Its shares are listed on India's two large stock exchanges, the Bombay Stock Exchange (BSE) and the National Stock Exchange (NSE). It employs over 5000 people across its global operations across 80 countries. The Company's Speciality business generated USD 303 Mn in Net sales in FY08.

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, undergoing Phase II clinical trials, has recently been out-licensed to Eli Lilly & company.

[[www.glenmarkpharma.com](http://www.glenmarkpharma.com)]

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

Shraddha Bothra,  
Manager, Corporate Communications  
Glenmark Generics Ltd.  
(T): +91 22] 4018 9913 (F): +91 22] 4018 9986  
E: [connect@glenmark-generics.com](mailto:connect@glenmark-generics.com)

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