

Press Release

For Immediate Dissemination

## **Glenmark's molecule for Rheumatoid Arthritis - GRC 4039, enters Phase I trials**

**Mumbai, February 21, 2008** – Glenmark Pharmaceuticals Ltd. [Glenmark] announced today that its candidate for Rheumatoid Arthritis, Inflammation and Multiple Sclerosis - **GRC 4039**, has entered Phase I trials. This is with approval from the Medicines and Healthcare Products Regulatory Agency [MHRA] in the U.K. The company intends to develop GRC 4039, a PDE 4 inhibitor, in Rheumatoid Arthritis as the primary indication. Glenmark expects to complete Phase I trials for GRC 4039 by October 2008 and initiate Phase II by January 2009.

GRC 4039, a selective PDE4 inhibitor is intended for rheumatoid arthritis [RA] and inflammatory disorders. After the withdrawal/setback of COX-2 Inhibitors and the void that exists in RA therapy for orally available potent small molecules, this is a potential block-buster opportunity in the global market.

Speaking on this development, Mr. Glenn Saldanha, MD & CEO, Glenmark Pharmaceuticals Ltd., said, "We are happy to take GRC 4039 forward into Phase I trials. This is Glenmark's fourth molecule to enter the clinics from our pipeline of eight NCEs and NBEs, and demonstrates our steady progress in the drug discovery space. RA has been selected as the primary indication for its commercial attractiveness, the unmet medical need for potent and convenient oral therapies and the sound biological rationale for PDE-4 inhibitor-based treatment in RA."

**GRC 4039** in pre-clinical testing has exhibited IC50 of 2.7nM; over 3700 fold selectivity to PDE4, good bioavailability across species and a long half-life indicating the potential for a once-daily dosing regimen. Additionally, there was no emesis in the pre-clinical models. The molecule demonstrated favourable results in early toxicology studies, a good safety margin and also exhibited good efficacy in *in-vivo* RA and TNF-  $\alpha$  inhibition models.

RA is a debilitating disorder with significant unmet need and attractive market dynamics. Approximately 1% of the global population is thought to be affected by the disorder, a systemic autoimmune disease that usually causes progressive symmetrical inflammation and damage of the joints by destroying the articular surfaces covering the bones. One in three RA patients is likely to be disabled within 20 years of disease onset due to rapid disease progression. Onset often occurs between the ages of 25 and 50 years and is two to three times more prevalent in women than in men.

## **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 and is focused in the areas of inflammation [Asthma/COPD, etc] and metabolic disorders [Diabetes, Obesity, etc].

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. Oglemilast is presently undergoing Phase II clinical trials in the US. The Company's second lead GRC 8200, a DPP-IV inhibitor for Type II Diabetes was out-licensed to Merck KGaA, Germany for the North American, European and Japanese markets. A third molecule targeting pain, GRC 6211, is undergoing Phase II clinical trials in Europe. Glenmark has three other programmes across obesity, inflammation and pain management at the pre-clinical stages; all of which should enter the clinics in by H1 FY 2008. [\[www.glenmarkpharma.com\]](http://www.glenmarkpharma.com)

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