

**Press Release** 

### **For Immediate Dissemination**

# **Enrollment Begins of First Patient in Phase II Vatelizumab Trial in Relapsing Remitting Multiple Sclerosis**

## Glenmark outlicensed Vatelizumab (GBR 500) to Sanofi for all indications in 2011

Mumbai – India, November 4, 2014: Glenmark announced today enrollment of the first patient in a multicenter Phase II clinical trial to evaluate Genzyme's investigational infusion therapy vatelizumab in patients with relapsing remitting multiple sclerosis (RRMS). The trial, called EMPIRE, is designed to assess the efficacy of vatelizumab vs. placebo in RRMS patients. The safety, tolerability and pharmacokinetics of vatelizumab will also be assessed.

Multiple sclerosis is a chronic inflammatory demyelinating and neurodegenerative disease of the central nervous system (CNS). Uncontrolled inflammation within the CNS leads to inflammatory damage that is associated with demyelinating lesions and neurodegeneration in patients with MS. Vatelizumab is a humanized monoclonal antibody that targets VLA-2, a collagen-binding integrin expressed on activated lymphocytes. The mechanism of action of vatelizumab is not known, although it is hypothesized to block VLA-2 on activated immune cells, leading to interference with collagen-binding in areas of inflammation, and thus may reduce the inflammatory cascade in MS.

Genzyme is developing vatelizumab in MS in partnership with Glenmark Pharmaceuticals. In addition to its marketed therapies, Genzyme has an MS R&D pipeline focused on investigational treatments to address unmet needs for relapsing and progressive forms of MS through research in selective immunomodulation, neuroprotection and remyelination.

Commenting on the progress with GBR 500, **Dr. Michael Buschle, President of Biologics and Chief Scientific Officer, Glenmark Pharmaceuticals Ltd.** said, "We are excited about the commencement of this trial and are pleased with the continued progress of our partnership with Sanofi/Genzyme."

#### About EMPIRE

EMPIRE is a global phase 2a/2b double-blind, randomized, placebo-controlled study assessing the efficacy, safety and dose-response of vatelizumab in patients with active RRMS. The study duration is 12 weeks. The study is expected to enroll 168 patients at 55 sites in 10 countries. For more information about the vatelizumab trial, visit www.clinicaltrials.gov.

## Glenmark Pharmaceuticals Ltd.



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

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company and ranked among the top 80 Pharma & Biotech companies of the world in terms of revenues. Glenmark is a leading player in the discovery of new molecules both NCEs and NBEs. Glenmark has several molecules in various stages of clinical development and primarily focused in the areas of Inflammation, Pain and Oncology. The company has significant presence in branded formulations across emerging economies including India. Its subsidiary, Glenmark Generics Limited services the requirements of the US and Western Europe markets.

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