

Press Release

For Immediate Dissemination

## Glenmark's TRPA1 antagonist 'GRC 17536' shows positive data in a proof of concept study

- Glenmark's first in class TRPA1 antagonist, GRC 17536, has shown positive data in a Phase 2a proof of concept study in patients with painful diabetic neuropathy

**September 17, 2014:** Glenmark Pharmaceuticals today announced that its first in class Transient Receptor Potential Ankyrin 1 (TRPA1) antagonist, GRC 17536 has shown positive data in a Phase 2a double blind, placebo controlled, multi-centre, proof of concept study conducted on 138 patients in Europe and India.

A statistically significant and clinically relevant response was seen in a prospectively-identified, substantial sub-group of patients with moderate to severe pain who had relatively intact sensory responses as detected by a standardized testing methodology. GRC 17536 was well-tolerated with no evidence of CNS or other drug related side effects.

Patrick Keohane, Chief Medical Officer, Glenmark stated "Diabetic neuropathy remains a difficult to manage chronic clinical condition with limited therapeutic options. These initial efficacy and safety data with GRC 17536, a peripherally acting novel therapeutic, are encouraging, and Glenmark intends to be ready to file for a Phase 2b dose range finding study in patients with neuropathic pain before the end of this financial year. This announcement also reaffirms our position globally in the development of novel pain therapies".

Commenting on this result, Dr. Michael Buschle, Chief Scientific Officer & President - Biologics, Glenmark Pharmaceuticals mentioned, "This is very promising and GRC 17536 may be useful for several indications which we will pursue".

The Glenmark TRPA1 program includes indications in pain as well as respiratory. Inhaled doses of GRC 17536 are also being tested in a Phase 2A proof of concept study in patients with Chronic Cough.

#### **Note on TRPA1**

TRPA1 is an ion channel expressed on peripheral and spinal sensory neurons and it mediates pain signal transmission. It functions as a cellular sensor for detecting painful mechanical, biochemical and thermal stimuli that cause sensory nerve hyperactivity during chronic pathologies including chronic pain, inflammation, itch and cough. TRPA1 receptor is shown to induce pain hypersensitivity in animal models of diabetic neuropathic pain and its blockade attenuates pain hypersensitivity as well as later loss of the nerve fibers and their function. GRC 17536 is a potent, selective and first in class antagonist of TRPA1 receptor. Preclinical studies have demonstrated its effectiveness in animal models of neuropathic and inflammatory pain including the peripheral diabetic neuropathic pain, osteoarthritic pain, postoperative pain and chemotherapy induced pain which supports potential utility of TRPA1 blockade in therapeutic pain management.

#### **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 as per SCRIP 100 Rankings. 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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