Press Release **For Immediate Dissemination**

Glenmark's novel molecule 'GRC 17536' for pain and respiratory entering human trials

- GRC 17536 targeting TRPA1 receptor is a potential first-in-class molecule globally
- The molecule has successfully completed pre-clinical trials and Phase I enabling studies. It has been filed for Phase I (human trials) in Europe
- The TRP family of ion channels have generated lot of interest globally due to their distinguishing role in pain signal transmission
- With this announcement, Glenmark has reaffirmed its position globally as a leader in the TRP space

February 17, 2011 : Glenmark Pharmaceuticals today announced that its Novel Chemical Entity(NCE) 'GRC 17536' is entering human trials. The new NCE program is targeting TRPA1 receptor antagonists for pain and respiratory disorders. TRPA1 belongs to Transient Receptor Potential (TRP) family of ion channels, which have generated a lot of interest as pain targets due to their distinguishing role in peripheral and/or central pain signal transmission.

Glenmark has completed animal trials and Phase 1 enabling GLP studies for its selected lead molecule, GRC 17536 and has filed the Phase 1 application for first-in-man trial in Netherlands. The Phase 1 studies are to be initiated soon and are likely to get completed before December 2011. Glenmark will also be initiating Phase 2 enabling studies shortly. In Phase I enabling studies, GRC 17536 was shown to be non-genotoxic and there were no safety concerns in GLP toxicology studies.

Glenn Saldanha, CEO & MD, Glenmark Pharmaceuticals ltd mentioned "We are excited that our TRPA1 discovery program is moving forward to human trials. This is another potential first-in-class molecule indicated for both pain and respiratory conditions. There is a huge unmet medical need in both therapeutic areas globally. GRC 17536 is highly selective even when compared with other TRPs and can be administered orally"

Glenmark is now positioned as one of the leading companies engaged in the discovery of novel TRP antagonists. Previously Glenmark has worked on TRPV1 and TRPV3 receptors and was able to successfully bring programs into clinical development. Both of these programs also resulted in out-licensing deals for Glenmark. To date, Glenmark has discovered several distinct scaffolds of highly potent TRPA1 antagonists with drug-like properties and has filed patent applications for these molecules.

GRC 17536, which is Glenmark's lead, is a highly potent (< 10nM) TRPA1 antagonist, which is highly selective (> 1000 fold over other TRPs) and orally available. It has proven highly efficacious in treating inflammatory and neuropathic pain in animal models compared to gold standard drugs. It reversed hyperalgesia in in-vivo models of Freund's complete adjuvant – induced inflammatory and chronic constriction injury (CCI) – induced neuropathic pain with an EC50 of less than 10 mg/kg. In addition, when tested in an in-vivo model of asthma, it showed promising effect on airway inflammation, bronchoconstriction and cough. In the Phase 1 enabling GLP studies, the compound has showed good safety in the genotoxicity, safety pharmacology and toxicology studies.

Note on TRPA1

Over the last decade, a lot of interest has been generated in transient receptor potential (TRPs) channels as pain targets due to their distinguishing role in peripheral and/or central pain signal transmission. The transient receptor potential ankyrin 1 (TRPA1) receptor is implicated in miscellaneous pathologies including noxious cold, chemical and mechanical induced pain and hyperalgesia conditions. TRPA1 gene knock-out studies resulted in impaired sensory function to noxious cold, chemical and mechanical stimuli, suggesting that TRPA1 represents an important target for development of therapeutics for inflammatory and neuropathic pain conditions. In animal studies, activation of TRPA1 by the noxious agents causes pain and neurogenic inflammation, which could be blocked by treatment with TRPA1 antagonists or gene-specific antisense oligonucleotides. Recently, TRPA1 receptor has been shown to mediate responses to major ingredients from cigarette smoke namely H2O2 and crotonaldehyde. Oxidant activation of airway neurons is known to induce respiratory depression, nasal obstruction, sneezing, cough, and pain and it is observed that all these responses are absent in TRPA1 deficient mice. These two observations suggest TRPA1 functional blockade as a promising approach in treating airway hyper-reactivity during asthma/COPD.

Addressable market

The addressable market for Asthma/COPD is approx USD 30 billion while the addressable market for osteoarthritis and neuropathic pain in approx USD 10 billion. There is a huge unmet medical need in both therapeutic areas.

About Glenmark Pharmaceuticals Ltd

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. It is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has eight molecules in various stages of clinical development and is primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain]. The company has a significant presence in branded generics markets across emerging economies including India. GPL along with its subsidiary has twelve manufacturing facilities in four countries and has five R&D centres.

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