**Hanmi Pharmaceutical and GC Biopharma Receives IND Clearance for Phase 1/2 Clinical Trial from the US FDA**

* **Co-development of innovative new drug for the treatment of Fabry disease as “the world’s first once-monthly subcutaneous treatment”**
* **Improves efficacy compared to existing treatment for kidney function, vascular disease, and peripheral nerve disorders**

Hanmi Pharm. Co., Ltd. announced that its collaborative project for Fabry treatment ‘LA-GLA’ (HM15421/GC1134A) with GC Biopharma has received Investigational New Drug (IND) clearance from the U.S. Food and Drug Administration (FDA) for a Phase 1/2 clinical trial.

LA-GLA is an innovative new drug for the treatment of Fabry disease as the world’s first once-monthly subcutaneous treatment, which is being co-developed by Hanmi Pharmaceutical and GC Biopharma. This clinical trial aims to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics of LA-GLA in patients with Fabry disease.

Fabry disease is a rare genetic disorder linked to the X chromosome and classified as a type of Lysosomal Storage Disease (LSD). It results from a deficiency in the enzyme alpha-galactosidase A, which is essential for breaking down glycolipids in lysosomes. The accumulation of glycolipids due to this deficiency leads to cellular toxicity and inflammatory responses, progressively damaging multiple organs and potentially leading to severe outcomes, including death.

Currently, Fabry disease is treated with Enzyme Replacement Therapy (ERT) which involves the intravenous administration of a recombinant enzyme. However, this treatment method requires patients to visit the hospital every two weeks for an infusion, leading to inconvenience. Moreover, the current method has limitations, including the burden of prolonged intravenous therapy and insufficient efficacy in preventing the progression of kidney disease.

LA-GLA is an ‘innovative enzyme replacement therapy” addressing the limitations of existing treatments. It significantly improves convenience with a once-monthly subcutaneous injection regimen. In preclinical studies, LA-GLA not only improves kidney function but also demonstrated superior efficacy in managing vascular disease and peripheral nerve disorders compared to existing therapies. Based on these promising results, it was designated as an Orphan Drug (ODD) by the U.S. FDA this past May.

Hanmi Pharmaceutical and GC Biopharma commented, “This collaboration integrates the latest FDA-mandated clinical protocols and leverages the specialized technical expertise of both companies, enabling a rapid transition into the clinical phase.” Further added, “Based on our expertise and knowledge of developing new treatments for Lysosomal Storage Disease (LSD), we will do our utmost to create new treatment options to patients suffering from Fabry disease.”

**<The End>**

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