

1 April 2020



Clinigen and GC Pharma collaboratively submit New Drug Application for Hunterase (Idursulfase-beta) ICV in Japan

Clinigen Group plc (AIM: CLIN, 'Clinigen' or the 'Group'), the global pharmaceutical and services company, and GC Pharma (KRX: 006280), the South-Korean biopharmaceutical company, announces today that Clinigen K.K., a wholly owned subsidiary of Clinigen, has submitted a New Drug Application (NDA) to the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan for Hunterase (Idursulfase-beta) ICV under the strategic alliance with GC Pharma.

Hunterase (Idursulfase-beta) ICV is an ICV formulation of human recombinant iduronate-2-sulfatase used in enzyme replacement therapy for patients with Hunter syndrome. Hunterase (Idursulfase-beta) ICV, originated by GC Pharma, is delivered directly to cerebral ventricles by intracerebroventricular (ICV) administration, in order to reach the cells of the brain and central nervous system.

The NDA submission follows the agreement signed with GC Pharma in April 2019, which was the first Japanese licensing agreement with an international company signed by Clinigen. Under the terms of the agreement, Clinigen will license and commercialise the product using its local expertise and infrastructure for the Japanese market.

Prior to its NDA Submission, Hunterase (Idursulfase-beta) ICV received Orphan Drug Designation (ODD) for the treatment of patients with Hunter syndrome in Japan on 17 March.

Hunter syndrome is a genetic, lysosomal storage disease which tends to affect approximately 1.3 out of 100,000 male newborns. The syndrome is caused by the lack of the enzyme, iduronate 2-sulfatase, which is responsible for breaking down and clearing complex sugars in the body. The build-up of these molecules eventually causes permanent, progressive damage affecting appearance, mental development, organ function and physical abilities and ultimately death at an early age.

Currently there is no cure for Hunter syndrome. Standard treatments are enzyme replacement therapy (ERT) or palliative care to manage symptoms.

Benjamin Miny, Executive Vice President of Commercial Medicines, Clinigen Group, said:

"Partnering with companies to commercialise their products outside of their home geography using Clinigen's regulatory expertise, is an important driver of growth for us in Japan. This NDA submission is another step in the process of licensing Hunterase, and in helping healthcare professionals to provide a treatment to their patients with conditions of high unmet medical need."

Eun Chul Huh, Ph.D., President, GC Pharma, said:

"We expect Hunterase to make to substantial improvement in the lives of those with Hunter syndrome. We will continue to invest in R&D to meet the unmet needs for rare disease treatment."

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Notes to Editors

About Hunter syndrome

Hunter syndrome (Mucopolysaccharidosis type II) is an inherited lysosomal storage disease that occurs primarily in boys. It causes an enzyme deficiency that interferes with the body's ability to break down certain complex sugars, resulting in serious skeletal, tissue, neurological and multi-organ complications and ultimately, death. It occurs in approximately 1.3 out of 100,000 male newborns. There is no cure. The standard treatments are enzyme replacement therapy (ERT) or palliative care.

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global pharmaceutical and services company with a unique combination of businesses focused on providing ethical access to medicines. Its mission is to deliver the right medicine to the right patient at the right time through three areas of global medicine supply; clinical trial, unlicensed and licensed medicines. The Group has sites in North America, Europe, Africa and Asia Pacific.

Clinigen now has over 1,100 employees across five continents in 14 countries, with supply and distribution hubs and operational centres of excellence in key long-term growth regions. The Group works with 22 of the top 25 pharmaceutical companies; interacting with over 15,000 registered users across over 100 countries, shipping approximately 6.4 million units in the year.

For more information on Clinigen, please visit www.clinigengroup.com

About GC Pharma

GC Pharma is a biopharmaceutical company that delivers life-saving and life-sustaining protein therapeutics and vaccines. Headquartered in South Korea, GC Pharma is one of the largest protein products manufacturers in the world and has been dedicated to quality healthcare solutions more than half a century. Green Cross Corporation updates its corporate brand as GC Pharma in early 2018. Green Cross Corporation remains the company's registered, legal name.