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Clinigen receives marketing approval for Hunterase (Idursulfase-beta) ICV in Japan

Clinigen Group plc (AIM: CLIN, 'Clinigen' or the 'Group'), the global pharmaceutical Products and Services company, today announces that Clinigen K.K., a wholly owned subsidiary of Clinigen headquartered in Tokyo, has received manufacturing and marketing approval for Hunterase (Idursulfase-beta) ICV 15mg, under its strategic alliance with GC Pharma. The approval in Japan is the first approval of Hunterase ICV in any country worldwide.

Hunterase has been approved as an enzyme replacement therapy for patients with Hunter syndrome (mucopolysaccharidosis type II). The product was developed by GC Pharma. It is delivered directly to cerebral ventricles by intracerebroventricular (ICV) administration, in order to reach the cells of the brain and central nervous system.

The product is expected to alleviate aspects of the disease such as delayed psychomotor development. In a phase I/II study conducted by Dr. Torayuki Okuyama, Department Head of Clinical Laboratory Medicine of the National Center for Child Health Development, data showed that Hunterase ICV significantly decreased heparan sulfate in cerebrospinal fluid, which is regarded as the key factor for delayed cognitive development.

An enzyme-replacement therapy drug for intravenous injection is already in use in Japan and other countries as a treatment for systemic symptoms of Hunter syndrome. However, no other drug targets the central nervous system symptoms, from which approximately 70% of patients suffer.

Sam Herbert, Chief Operating Officer, Clinigen Group, said:

"Receiving this manufacturing and marketing approval is positive news, representing another example of Clinigen supporting innovation and utilising its global platform to provide access to the right medicines for patients. We can now offer an important drug in ICV form to physicians for their patients with Hunters syndrome."

Takashi Matsuki, Representative Director and General Manager, Clinigen K.K., said:

"*We are delighted to have received manufacturing and marketing approval in Japan for Hunterase ICV, through our partnership with GC Pharma. We are striving to provide Hunterase ICV to patients with mucopolysaccharidosis type II in Japan as soon as possible, in keeping with our Group's mission of 'right medicine, right patient, right time.'"*

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

"This approval represents a great triumph of community involvement to address the significant unmet need of slowing the cognitive decline in MPS II patients. It is a result of patients, physicians and other collaborative efforts."

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Notes to Editors

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global pharmaceutical Products and Services company focused on providing ethical access to medicines with a mission to deliver the right medicine to the right patient at the right time. The Group operates from sites in North America, Europe, Africa and Asia Pacific.

Clinigen now has over 1,150 employees across five continents in 16 countries, with supply and distribution hubs and operational centres of excellence in key long-term growth regions. The Group works with 21 of the top 25 pharmaceutical companies; interacting with over 18,000 registered users across over 115 countries, shipping approximately 6.5 million units in the year.

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

About Clinigen K.K.

Clinigen K.K. is a fully owned subsidiary of Clinigen plc (listed on London's Alternative Investment Market), a company engaged in a range of pharmaceutical-related business, with its headquarters in Burton-on-Trent, UK. In Japan, Clinigen K.K. works on the development, manufacture and marketing of orphan drugs and pharmaceuticals for niche markets.

In collaboration with our fellow group company, Link Healthcare, headquartered in Chuo-ku, Tokyo, Clinigen K.K. provides an early-access program (EAP) for Japanese pharmaceutical manufacturers to supply unapproved drugs for humanitarian use, together with consulting services to facilitate the use of this program.

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. It occurs in approximately 1.3 out of 100,000 male newborns. There is no definitive cure. The standard treatment is enzyme replacement therapy (ERT).

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.