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Clinigen and GC Pharma sign exclusive licensing agreement 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, have signed an exclusive licensing agreement to commercialise Hunterase (Idursulfase-beta) ICV in Japan.

This is the first Japanese licensing agreement with an international company signed by Clinigen. Clinigen will license and commercialise the product using its local expertise and infrastructure. Once commercialised, Hunterase (Idursulfase-beta) ICV will become the Group's second licensed product alongside Foscavir.

Hunterase (Idursulfase-beta) ICV is a human recombinant iduronate-2-sulfatase used in enzyme replacement therapy for patients with Hunter syndrome. Hunterase (Idursulfase-beta) ICV developed 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.

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, Senior Vice President of Commercial Medicines, Clinigen Group, said:

"We are proud to be partnering with GC Pharma, to be able to help healthcare professionals in Japan provide a treatment to their patients with this complex disease and high unmet medical need. At a company level, this is also a great achievement for our team in Japan and demonstrates our ability to partner with pharmaceutical companies outside their home geographies to commercialise their products. We will use our expertise in Japanese regulatory affairs to manage the process of licensing Hunterase to make this treatment available as soon as possible."

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

"We are delighted to further enhance the value of Hunterase through this partnership and look forward to working with the Clinigen team. Our efforts to make substantial differences in the lives of those with Hunter syndrome in all markets will continue by providing new treatment environments and opportunities."

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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. In October 2018, the Group acquired CSM, a specialist provider of packaging, labelling, warehousing and distribution services, with sites in the US and Europe, and iQone, a specialist pharmaceutical company in Switzerland.

For more information, 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.