GC Pharma and Speragen Announce Joint Development of SSADHD Enzyme Replacement Therapy and License Agreement of the patent of SSADH Protein generation plasmid

- Collaboration to focus on developing First-in-Class drug to fulfill unmet needs of patients

YONGIN, SOUTH KOREA & AUSTIN, TX, USA, 19 July 2021 – GC Pharma (006280.KS) and Speragen, Inc. today announced that they have completed the signing of partnership to co-develop Enzyme Replacement Therapy (ERT) for SSADHD (Succinic Semialdehyde Dehydrogenase Deficiency), a disorder caused by mutations in the ALDH5A1 gene which is inherited in an autosomal recessive manner.

The collaboration aims to develop first-in-class SSADHD ERT using intact SSADH proteins delivered to mitochondria. Under the terms of the agreement, Speragen will receive an undisclosed upfront payment, further milestone payments and royalties on sales of resulting products from GC Pharma. GC Pharma obtains an exclusive global sublicense right to Speragen's patent for SSADH protein encoding plasmid, which is originally licensed by Washington State University (WSU).

As part of the agreement, Speragen, Inc. will conduct an externally lead patient-focused drug development (PFDD) in accordance with FDA Prescription Drug User Fee Act (PDUFA) V and neonatal (or newborn) screening for early identification of afflicted patients. GC Pharma, with its ERT expertise from its own product HUNTERASE, will concentrate on manufacturing and controls (CMC), clinical and nonclinical trials, patent and approval, natural history study (NHS) and biomarker study of SSADHD ERT. Both parties plan to go through preclinical studies from this year to the second half of 2023, the expected time for a Phase I/II clinical trial.

"This collaboration is a part of our commitment to solving an incurable rare disorder," said EC Huh, Ph. D., President of GC Pharma. "We will continue to reinforce R&D pipeline to meet the unmet needs for rare disease treatment."

"This is an exciting day for the SSADHD community, after decades of work, bringing hope to the patients and families afflicted with this devastating disorder," said Alice McConnell CEO and Co-Founder of Speragen. "GC Pharma's solid track record and development expertise makes for the ideal collaboration partner".

About SSADHD

Succinic semialdehyde dehydrogenase deficiency (SSADHD) is a disorder that can cause a variety of neurological and neuromuscular problems. The signs and symptoms can be extremely variable among affected individuals and may include mild to severe intellectual disability; developmental delay (especially involving speech); hypotonia; sleep disturbances; difficulty coordinating movements (ataxia); and/or seizures. Some affected individuals may also have decreased reflexes (hyporeflexia); nystagmus; hyperactivity; and/or behavioural problems. SSADH deficiency is caused by mutations in the *ALDH5A1* gene and is inherited in an autosomal recessive manner. Management in generally symptomatic and typically focuses on treating seizures and neurobehavioral issues. Like so many rare diseases, there is no treatment for SSADHD in worldwide.

About GC Pharma

GC Pharma (formerly known as Green Cross Corporation) is a biopharmaceutical company that delivers life-saving and life-sustaining protein therapeutics and vaccines. Headquartered in Yongin, South Korea, GC Pharma is one of the leading plasma protein and vaccine product manufacturers globally and has been dedicated to quality healthcare solutions for more than half a century. Green Cross Corporation updated its corporate brand to GC Pharma in early 2018. Green Cross Corporation remains the company's legal name.

This press release may contain forward-looking statements, which express the current beliefs and expectations of GC Pharma's management. Such statements do not represent any guarantee by GC Pharma or its management of future performance and involve known and unknown risks, uncertainties and other factors. GC Pharma undertakes no obligation to update or revise any forward-looking statement contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule.

About Speragen, Inc.

Speragen was co-founded by a mother of two children who are affected with SSADHD. Speragen knows first-hand the challenges of navigating a life with a rare disease: from the daily challenges, the diagnostic odyssey, accepting the new reality post-diagnosis, finding a team of knowledgeable clinicians who can provide care, and finally to seeing the chasm between the current state of treatment and the possibility of a first-in-class drug becoming available. Speragen, comes from the Latin word “spera” meaning “hope”. It was formed to help solve these issues more rapidly by bridging the gulf from hope to the realization of a therapy.

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