



## Press Release

### **CMC Biologics and Genexine, Inc. Announce Manufacturing Agreement for Genexine's Human Growth Hormone Drug, GX-H9**

BOTHELL, Washington, U.S.A., and SEONGNAM, Republic of Korea, February 16, 2017 - CMC ICOS Biologics, Inc. ("CMC Biologics"), a global leader in clinical and commercial manufacturing of therapeutic proteins, and Genexine, Inc. (KOSDAQ: 095700), an innovative biotechnology company focused on immuno-oncology, metabolic and orphan diseases, today announced that they have entered into a manufacturing agreement for the process transfer and cGMP manufacturing of Genexine's GX-H9.

GX-H9, being co-developed with Handok under a strategic partnership, is next-generation, long-acting recombinant human growth hormone (rhGH) consisting of recombinant growth hormone genetically fused to Genexine's proprietary hybrid Fc (hyFc) platform, giving it extended half-life and potentially better safety profile. Compared to the current daily injection therapy, GX-H9 is being evaluated as weekly and twice-monthly dosing regimens to treat Growth Hormone Deficiency (GHD) in adult and pediatric patients. The US FDA Office of Orphan Products Development (OOPD) has granted GX-H9 orphan drug designation for the treatment of growth hormone deficiency.

"We have selected CMC Biologics as our manufacturing partner for GX-H9 because of their demonstrated technical expertise and the quality of their cGMP operations," said Dr. Michael Keyoung, Genexine's President & Chief Executive Officer. "The successful transfer and manufacture of GX-H9 is critical to meeting our clinical timelines as we advance our lead candidate towards a pivotal study and we believe that CMC can take us there."

Human growth hormone (hGH) is a polypeptide hormone consisting of 121 amino acids. It is produced by the pituitary gland located in the lower part of the brain and promotes growth and development of human body. hGH plays a critical role in the human metabolic system, stimulating synthesis of proteins and the absorption of amino acids at the cellular level. hGH stimulates production of IGF-1 insulin-like growth factor 1 (IGF-1) in the liver, which has growth-stimulatory effects on variety of tissues including muscles and bone tissue. The level of hGH increases through childhood and adolescence. It is present at the most optimum level during the age of 15 years to 30 years but declines with age.

"As human growth hormone plays a critical role in the human metabolic system, GX-H9 will be critical for both children and adult with hormone deficiency to receive this drug. We are very excited to be working with Genexine, to help these patients potentially live their lives as normal as possible after treatment," said Gustavo Mahler, PhD, Global Chief Executive Officer & President of CMC Biologics.

The key function of hGH is growth and is responsible for increasing height. Thus in children and adolescents, deficiency of hGH or Growth Hormone Deficiency (GHD) can thus lead to dwarfism, delay in sexual maturity or growth delay. In adult, shortage in hGH can adversely affect the overall quality of life including reduction in social, mental and physical energy; reduction in muscle mass, increase in body fat, increase in cholesterol level, higher cardiovascular disease rates and lower bone density.



### **About CMC Biologics**

CMC Biologics is leading the industry among CMOs in reliability, technical excellence, and quality — Right and On Time. With three facilities in the USA and Europe, the Company provides fully integrated biopharmaceutical development and manufacturing solutions to clients globally. The Company has proven expertise in delivering custom solutions for the scale-up and cGMP manufacture of protein-based therapeutics for pre-clinical, clinical, and commercial production. The Company's wide range of integrated services includes cell line development, bioprocess development, formulation development, and comprehensive analytical testing. Clients can also benefit from CMC Biologics' proprietary CHEF1® expression system for mammalian production. CMC Biologics has fully segregated microbial fermentation and mammalian cell culture suites and offers both fed-batch and perfusion production processes. More detailed information can be found at [www.cmcbio.com](http://www.cmcbio.com)

### **About Genexine, Inc.**

Genexine, Inc., listed on KOSDAQ (095700) since 2009, is a leading biotherapeutics company focused on immuno-oncology and metabolic/autoimmune diseases. Genexine has robust pipelines in clinical and pre-clinical stages based on long-acting Fc fusion technology and therapeutic DNA technology. In the clinical stage, Genexine has GX-H9 (long-acting recombinant human growth hormone, rhGH-hyFc) for both adult and pediatric GHD, currently in multinational phase II trials. GX-188E therapeutic DNA vaccine for HPV-associated diseases is in Phase II in Europe and Korea for Cervical Intraepithelial Neoplasia II/III and plans to enter into Phase 1b/2a trial in cervical cancer with GX-188E in combination Keytruda (anti- PD-1 therapy) of Merck (also known as MSD) 1H of 2017. Founded in 1999, Genexine has over 150 employees and half of them are scientists with MSc or Ph.D. Genexine is located in Pangyo Techno Valley near Seoul, Korea with a branch office in New York. More information can be found at [www.genexine.com](http://www.genexine.com)

### **About Handok, Inc**

Handok (Chairman & CEO Young-Jin Kim), listed on KOSPI(002390) is a leading innovation-driven pharmaceutical/health-care company in Korea. Handok develops, manufactures and distributes healthcare solutions to improve the health and quality of human life. Handok has a core business focus on diabetes, cardiovascular, muscular skeletal, psychoneurotic disease, human vaccines, medical devices, diagnostics and consumer health. Handok, founded in 1954, grew as a joint venture with Hoechst/Aventis/Sanofi from 1964 to 2012. Handok has also established strategic collaborations in several areas with multiple multinational pharmaceutical companies. More information can be found at [www.handok.co.kr](http://www.handok.co.kr)

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