



Press release
29 December, 2021

Kringle Pharma Strengthens IP Portfolio with the Formulation Patent in Europe

Kringle Pharma, Inc. (Head office located in Ibaraki, Osaka; President & CEO, Kiichi Adachi; “KRINGLE”), a late clinical-stage biopharmaceutical company, today announces that the European Patent Office has issued patent No. EP3192524, entitled “HGF PREPARATION SUITABLE FOR TREATMENT OF NERVOUS DISEASES”. This patent covers proprietary formulations of drug product containing recombinant human hepatocyte growth factor (HGF). A drug product based on the patented formulation has been used in the ongoing clinical studies including Phase 3 in acute spinal cord injury and Phase 2 in amyotrophic lateral sclerosis (ALS). Besides, Phase 1/2 study in vocal fold scar was successfully completed with the same investigational drug to be administered locally in the vocal cords (Hirano *et al.*, J Tissue Eng Regen Med. 2018; 12(4):1031-1038). Therefore, the patented drug formulation can be utilized not only for neuronal diseases but also other incurable diseases such as vocal fold scar, being the basis of expanding the target indications for HGF treatment. This patent was already granted in the U.S., Japan, Canada and Korea, further strengthening the Kringle’s intellectual property position globally.

About Hepatocyte Growth Factor (HGF)

HGF was originally discovered as an endogenous mitogen for mature hepatocytes. Subsequent studies demonstrated that HGF exerts multiple biological functions based on its mitogenic, motogenic, anti-apoptotic, morphogenic, anti-fibrotic and angiogenic activities, and facilitates regeneration and protection of a wide variety of organs including not only liver, but also kidneys, heart, lungs, nerve tissues and skin. Therapeutic effects of HGF administration in model animals of intractable diseases have been reported in many scientific papers, and expectations for HGF as a novel therapeutic agent for intractable diseases are increasing.

About Kringle Pharma, Inc. <https://www.kringle-pharma.com/en/>

Kringle Pharma is a late clinical-stage biopharmaceutical company established in December 2001 to develop novel biologics based on HGF. Currently, Kringle’s clinical programs with recombinant human HGF are: 1) Phase 3 ongoing in acute spinal cord injury, 2) investigator-initiated Phase 2 ongoing in ALS, 3) Phase 2/3 in preparation in vocal fold scar, and 4) Phase 1a and 1b completed in acute kidney injury. Kringle’s mission is to contribute to societal and global healthcare through the continued research, development and commercialization of HGF drug for patients suffering from incurable diseases.

For more information, please contact:

Daichika Hayata

Director, Pharmaceutical Development

Kringle Pharma, Inc.

☎ +81-72-641-8739

✉ kpinfo@kringle-pharma.com