



Kringle
Pharma

Press release

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Kringle Initiates Phase 1 Clinical Trial of Recombinant Human HGF for the Treatment of Incurable Neurological Diseases

Kringle Pharma, Inc. (“KRINGLE”) proudly announces that it has achieved an approval from Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) to launch a phase 1 clinical trial of recombinant human hepatocyte growth factor (rhHGF) for incurable neurological disease therapy. rhHGF has been shown in preclinical models to promote neuronal survival, prevent neuronal cell death, accelerate angiogenesis and reduce gliosis. KRINGLE has been developing rhHGF for the treatment of incurable neurological diseases in cooperation with Professor Masashi Aoki, Department of Neurology, Tohoku University School of Medicine, Associate Professor Hiroshi Funakoshi, Research Center for Brain Function and Medical Engineering, Asahikawa Medical University, Professor Hideyuki Okano, Department of Physiology, Keio University School of Medicine and Professor Yoshiaki Toyama, Department of Orthopedic Surgery, Keio University School of Medicine. All are members of the Japanese national program for advanced medical development.

The phase 1 clinical trial is intended to assess the safety and pharmacokinetics of single dose and multiple doses of rhHGF in patients with amyotrophic lateral sclerosis (ALS). The trial will take place in Tohoku University Hospital.

Kunio Iwatani, President and CEO of KRINGLE stated, “Along with the ongoing phase 1b clinical trial in the US of rhHGF for renal diseases, KRINGLE is now set to launch its first clinical trial in Japan. The simultaneous clinical studies of rhHGF in Japan and the US will doubtless accelerate product development and submissions. KRINGLE will continue to make every effort toward proof of concept validation and clinical efficacy with the ultimate goal of providing novel and innovative therapies for patients suffering from these and other incurable diseases”.

About Hepatocyte Growth Factor (HGF)

Hepatocyte growth factor (HGF), a ligand for the c-Met receptor tyrosine kinase, has mitogenic, motogenic, morphogenic and anti-apoptotic activities for various epithelial cells, while it has an angiogenic action for endothelial cells. It is acting in a principal role of regeneration and protection of tissues caused by injury and disease. Physiologically, HGF has an organotrophic role in the regeneration and protection of various organs, including the liver, lung, stomach, pancreas, heart, neurons and kidneys. It is therefore expected to have widespread clinical application in a number of therapeutic areas – renal, cardiovascular, hepatic, and CNS.

About Kringle Pharma, Inc.

Kringle Pharma is a clinical-stage biopharmaceutical company established in December 2001 to develop novel biologics based on HGF. Currently, Kringle’s ongoing clinical projects on HGF are treatment of 1) acute renal failure and 2) incurable neurological diseases. For more information, please refer to the company’s website: www.kringle-pharma.com/en/index.html



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About Amyotrophic Lateral Sclerosis (ALS)

ALS, characterized by muscle atrophy and weakness to the patients, is a progressive incurable neurological disease associated with selective disorder of motor neurons. The symptoms include ambulation difficulty, dysarthria (disturbance of speech), dysphagia (disorder of swallowing), and respiratory compromise. The incidence of ALS is two per 100,000 people. There are approximately 8,500 ALS patients in Japan, 30,000 in the US and 350,000 worldwide. The cause of ALS is not fully understood yet. It is estimated only 50% of those diagnosed with ALS survive for more than 3 years.

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