



22 December, 2017

Kringle Completes Participant Enrollment in the Phase I/II Trial of Recombinant Human HGF for the Treatment of Acute Spinal Cord Injury

Kringle Pharma, Inc. (“KRINGLE”) is pleased to announce completion of enrollment in the Phase I/II clinical trial of recombinant human hepatocyte growth factor (rhHGF) for people with acute spinal cord injury, since the number of the cases necessary for the statistical analysis has been successfully accumulated.

This double-blind, placebo-controlled Phase I/II trial is being conducted to assess safety and efficacy of the rhHGF treatment in people with acute spinal cord injury, recruited at three specialized hospitals in Japan: Spinal Injuries Center, Hokkaido Spinal Cord Injury Center and Murayama Medical Center. The trial will proceed with the follow-up of all participants, then breaking the blind followed by detailed statistical analysis. A clinical study report of the Phase I/II trial will be finalized in the fourth quarter of 2018.

The therapeutic effects of rhHGF on spinal cord injury have been demonstrated in rat and marmoset disease models by Professors Hideyuki Okano and Masaya Nakamura’s group at Keio University School of Medicine. KRINGLE has been collaborating with Professors Okano and Nakamura for many years and, based thereon, KRINGLE has promoted the clinical development of rhHGF as a therapeutic agent for spinal cord injury.

Kiichi Adachi, President and CEO of KRINGLE stated, “We are pleased to announce that we have enrolled the last participant in the Phase I/II trial according to the very strict inclusion criteria. We would like to express our sincere gratitude for the cooperation of the spinal cord injury people who participated in this study, as well as the doctors and staff in the clinical trial sites. Unmet medical need in the treatment of acute spinal cord injury is quite obvious and the development of a safe and effective novel drug has been strongly desired. We are confident that rhHGF treatment to people with acute spinal cord injury will reduce spinal cord damage to certain extent, and people suffering injury will be able to make a significant functional recovery through rehabilitation and even cell transplantation therapy under development. Thus, it is anticipated that rhHGF will not only improve the QOL of spinal cord injury people but also reduce the burden placed on caregivers.”

KRINGLE's project entitled 'Recombinant human HGF for the treatment of acute spinal cord injury' has been supported by Japan Agency for Medical Research and Development (AMED) as its Adaptable and Seamless Technology Transfer Program (A-STEP) in the past, and its Drug Discovery Support Promotion Project currently.



About Hepatocyte Growth Factor (HGF)

HGF was originally found to be a mitogen for mature hepatocytes, and subsequent studies elucidated that HGF acts on various epithelial and vascular cells. HGF facilitates regeneration and protection of tissues damaged by injury and disease through its mitogenic, motogenic, and morphogenic properties as well as anti-apoptotic and angiogenic activities. In the brain and nerve tissues, HGF exerts neurotrophic effects and enhances neurite outgrowth. The therapeutic effects of rhHGF on spinal cord injury and amyotrophic lateral sclerosis (ALS) have been demonstrated in animal models by the group at Keio University described above, and Professor Masashi Aoki at Tohoku University, respectively. Based on these preclinical results, it is anticipated that rhHGF will be an effective and novel drug in the treatment of incurable neuronal diseases.

About Spinal Cord Injury

Spinal cord injury is caused by trauma, leading to a variety of paralytic or painful symptoms. In descending order of incidence, traffic accidents and falls from height are the main causes of spinal damage. Recently, due to the decrease in traffic accidents and the rise in the elderly population, slight fall is becoming an increasingly common cause. Approximately 5,000 people incur spinal cord injury each year in Japan. By appropriate early treatment after the injury and specialized rehabilitation, some degree of functional recovery can be expected, but complex severe symptom, including motor paralysis, muscular spasticity, sensory paralysis, dysfunction of internal organs (rectal and bladder disorder, thermoregulatory dysfunction, decreased visceral function, decreased respiratory function) may often remain. For these reasons, therefore, there is a strong need for the development of a novel drug.

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

Kringle Pharma is a clinical-stage biopharmaceutical company established in December 2001 to develop novel biologics based on HGF. Currently, Kringle's clinical projects on rhHGF are as follows: 1) Phase I/II ongoing in acute spinal cord injury, 2) investigator-initiated Phase II ongoing in ALS, 3) Phase Ia and Ib completed in acute kidney injury, and 4) investigator-initiated Phase I/II completed in vocal fold scar.

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