Press release
20 July, 2020

Kringle Initiates Phase 3 Clinical Trial of Recombinant Human HGF for the Treatment of Acute Spinal Cord Injury

Kringle Pharma, Inc. (Head office located in Ibaraki, Osaka; President & CEO, Kiichi Adachi; "KRINGLE") today announced the initiation of a Phase 3 clinical trial to evaluate and confirm the therapeutic efficacy of recombinant human hepatocyte growth factor (KP-100IT) in subjects with acute spinal cord injury. KRINGLE submitted a clinical trial notification to the Japanese regulatory agency, Pharmaceuticals and Medical Devices Agency (PMDA), on June 9, 2020. This Phase 3 clinical trial, to be conducted in Japan, is a nonrandomized, multicenter, confirmatory trial in 25 subjects with severe cervical spinal cord injury.

KRINGLE recently completed a double-blind, placebo-controlled Phase 1/2 clinical trial of KP-100IT in subjects with the acute phase of spinal cord injury. The trial achieved positive clinical outcomes in both the evaluation of KP-100IT's safety and efficacy in this subject population. Upon a review of these data, the Japanese Ministry of Health, Labour and Welfare granted an orphan drug designation to KP-100IT. These data and results were recently published in the Journal of Neurotrauma (May 22, 2020, online).

This Phase 3 confirmatory trial, led by Professor Masaya Nakamura at Keio University School of Medicine as coordinating investigator, will be conducted at the three (3) national hospitals in Japan specialized for the treatment of patients with spinal cord injury:

-Spinal Injuries Center (Iizuka, Fukuoka)
-Hokkaido Spinal Cord Injury Center (Bibai, Hokkaido)
-Murayama Medical Center (Musashimurayama, Tokyo)

(Note: Study details on the Phase 3 clinical trial was registered at ClinicalTrials.gov (NCT04475224)).

"In the treatment of spinal cord injury, it is most important to suppress the secondary degeneration in which the damaged area expands due to inflammatory reactions after injury", said Kiichi Adachi, Ph.D., President and CEO of KRINGLE. "HGF has the action of suppressing the secondary degeneration that occurs during the acute phase of spinal cord injury, and the treatment with KP-100IT is ideally suited for the acute phase treatment because of its safety profile and the convenience of the preparation that can be administered immediately after injury. KRINGLE plans to complete this Phase 3 clinical trial and subsequently apply for manufacturing and marketing approval in Japan. KRINGLE aims to improve the prognosis of spinal cord injury subjects and reduce the burden on caregivers by socially implementing KP-100IT as a novel orphan drug therapy for the treatment of acute spinal cord injury".

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 HGF on spinal cord injury have been demonstrated in animal models by Professors Hideyuki Okano and Masaya Nakamura at Keio University School of Medicine. Based on these preclinical results, clinical development of KP-100IT recombinant human HGF was undertaken for the treatment of acute spinal cord injury.

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. https://www.kringle-pharma.com/en/

Kringle Pharma is a late-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 in acute spinal cord injury (ongoing), 2) investigator-initiated, double-blind, placebo-controlled Phase 2 in amyotrophic lateral sclerosis (ALS) (ongoing), 3) Phase 1a and 1b in acute kidney injury (completed), and 4) investigator-initiated Phase 1/2 in vocal fold scar (completed). Kringle's mission is to contribute to societal and global health through the continued research, development and commercialization of HGF for patients suffering from incurable diseases.

For more information, please contact:
Etsuro Hashimura
Director of Pharmaceutical Development, Member of the Board
Kringle Pharma, Inc.
☎ +81-72-641-8739
✉ kpinfo@kringle-pharma.com