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

Kringle Pharma, Inc. (“KRINGLE”) today announced the initiation of a phase I/II clinical trial in people with acute spinal cord injury to assess the safety and efficacy of recombinant human hepatocyte growth factor (rhHGF). KRINGLE submitted a clinical trial notification to the Japanese regulatory agency, Pharmaceuticals and Medical Devices Agency (PMDA) in March 3, 2014. The study protocol was conceived and designed in consultation with PMDA. This study is being conducted with support from Adaptable and Seamless Technology transfer Program (A-STEP) of the Japan Science and Technology Agency (JST).

Kunio Iwatani, President and CEO of KRINGLE stated, “There are not many drugs for spinal cord injury and their therapeutic benefits are quite limited, with substantial side effects. Therefore, there exists a clear need for the development of a safe and effective novel drug. If treatment of acute spinal cord injury with rhHGF can reduce spinal cord damage to some extent, people suffering injury will be able to make a significant functional recovery through rehabilitation, or the transition to chronic complete lesion will be suppressed. Thus, it is anticipated that rhHGF will not only improve the QOL of people with spinal cord injury but also reduce the burden placed on caregivers.”

KRINGLE has been developing rhHGF for the treatment of incurable neurological diseases in cooperation with Professor Hideyuki Okano, Department of Physiology, Keio University School of Medicine; Professor Yoshiaki Toyama, Department of Orthopedic Surgery, Keio University School of Medicine; Professor Masashi Aoki, Department of Neurology, Tohoku University School of Medicine; Professor Yasuto Itoyama, Vice-President of International University of Health and Welfare; and Professor Hiroshi Funakoshi, Center for Advanced Research and Education, Asahikawa Medical University, under the Japanese national program for advanced medical development. As a result, KRINGLE has already begun conducting a phase I clinical trial in amyotrophic lateral sclerosis (ALS) at Tohoku University Hospital. The initiation of this phase I/II clinical trial in acute spinal cord injury is another milestone achievement for the continued collaboration.

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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 have been demonstrated in rat and marmoset models of contusive spinal cord injury by Professors Okano and Toyama's group at Keio University School of Medicine. Based on these preclinical results, it is anticipated that rhHGF will be an effective and novel drug in the treatment of 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. 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.

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 rhHGF are treatment of 1) acute kidney injury and 2) incurable neurological diseases. For more information, please refer to the company website: www.kringle-pharma.com/en/index.html

About Phase I Clinical Trial in Amyotrophic Lateral Sclerosis (ALS)

The phase I clinical trial in ALS patients to assess the safety and pharmacokinetics of single dose and multiple doses of rhHGF is currently ongoing. Patient enrollment in this study has already closed.