Press release
13 April 2023

Last Patient Enrolled in Phase III Study for the Treatment of Acute Spinal Cord Injury

Kringle Pharma, Inc. (Head office located in Osaka, Japan; President & CEO, Kiichi Adachi; "KRINGLE"), a late clinical-stage biopharmaceutical company, today announced the completion of patient enrollment in its ongoing Phase III clinical study of KP-100IT, the intrathecal formulation of recombinant human HGF, in patients with acute spinal cord injury. The study enrolled 25 patients at 5 clinical sites. Following the six-month observation period of the last patient, KRINGLE will conduct the efficacy and safety analysis with all subjects and then report top-line results from the study.

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. HGF exerts neurotrophic effects and enhances neurite outgrowth, and the therapeutic effect of HGF on spinal cord injury has been demonstrated in animal models by Professors Hideyuki Okano and Masaya Nakamura at Keio University School of Medicine. Expectations for HGF as a novel therapeutic agent are increasing for 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, tripping over, traffic accidents and falls from height are the main causes of spinal damage. Recently, due to the rise in the elderly population, tripping over is becoming an increasingly common cause. In Japan, there are approximately 100,000 to 200,000 chronic spinal cord injury subjects with an incidence of about 6,000 new cases per year*. 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.

*Source:

Miyakoshi N et al. Spinal Cord 2021 Jun;59(6):626-634.
Sakai H et al. J Spine Res. 2010 1(1):41-51.

In parallel with the ongoing Phase III study, KRINGLE launched a collaborative research program with Professors Hideyuki Okano and Masaya Nakamura at Keio University School of Medicine in 2021, aiming to create next-generation therapies for spinal cord injury. In this research, transplantation of human iPS cell-derived neural stem/progenitor cells owned by Keio University, combined with scaffold-mediated delivery of HGF developed by KRINGLE demonstrated the restoration of locomotor and urinary functions for the first time in the world in the rodent model of chronic complete spinal cord transection. Based on this innovation, KRINGLE and Keio University jointly filed a patent application (Please see the news release

dated March 11, 2022). It is no doubt that these results mark an important milestone toward delivering a novel combination therapy to combat chronic complete spinal cord injury, in which the functional recovery has been considered extremely difficult.

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

Kringle Pharma is a late clinical-stage biopharmaceutical company established in December 2001, focused on development of novel biologics based on HGF. Currently, Kringle conducts two Phase III clinical studies, which is the final stage of the drug development, in acute spinal cord injury and vocal fold scar among other target indications. 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.

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