Press release
13 May, 2022

Kringle Pharma Provides an Update on Progress of Phase 3 Clinical Trial in Patients with 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 provides an update on Phase 3 clinical trial of KP-100IT, the intrathecal formulation of recombinant human HGF, in patients with acute spinal cord injury. This trial is currently ongoing at five clinical trial sites in Japan, with the estimated enrollment of 25 participants. Since the start of the trial in July 2020, patient enrollment was progressing approximately at the expected pace until recently. Due to the impact of the latest re-expansion of COVID-19 in Japan, however, the enrollment pace is slowing down and the enrollment has not reached the target number as of today. Under those uncertain circumstances of the COVID-19 pandemic, KRINGLE has submitted the notification to PMDA (Pharmaceuticals and Medical Devices Agency) to extend the study period for six months. KRINGLE continues close collaboration with the clinical trial sites aiming to complete the patient enrollment in the second half of 2022, expecting the last patient out in the first half of 2023.

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 effects of HGF on spinal cord injury and ALS have been demonstrated in animal models by Professors Hideyuki Okano and Masaya Nakamura at Keio University School of Medicine and Professor Masashi Aoki at Tohoku University School of Medicine, respectively. Expectations for HGF as a novel therapeutic agent are increasing for such intractable 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, 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.

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

Kringle Pharma is a late clinical-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 ongoing in acute spinal cord injury, 2) investigator-initiated Phase 2 ongoing in ALS, 3) Phase 2/3 in preparation in vocal fold scar, and 4) Phase 1a and 1b completed in acute kidney injury. 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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