



Press release  
13 January 2023

## **The Latest 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. KRINGLE was previously expecting to complete patient enrollment by the end of 2022. As of today, however, although more than 90% of the target subjects has been recruited, patient enrollment has not been completed yet primarily due to the prolonged impact of COVID-19 pandemic. KRINGLE continues to enroll patients until it reaches the target number, in close cooperation with the clinical trial sites in order to complete the study as soon as possible.

### ***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.

### **For more information, please contact:**

Daichika Hayata

Director of Pharmaceutical Development, Member of the Board

Kringle Pharma, Inc.

☎ +81-72-641-8739    ✉ [kpinfo@kringle-pharma.com](mailto:kpinfo@kringle-pharma.com)