



Press release  
9 December, 2021

## **Last Patient Out in Phase 2 Study of KP-100IT for the Treatment of ALS**

Kringle Pharma, Inc. (Head office located in Ibaraki, Osaka; President & CEO, Kiichi Adachi; “KRINGLE”), a late clinical-stage biopharmaceutical company, today announces that the last patient has now completed the treatment and follow-up in the randomized, double-blind, placebo-controlled Phase 2 study of KP-100IT in ALS. The study outline is registered in the UMIN Clinical Trials Registry with the ID No. UMIN000022050, as follows:

[https://upload.umin.ac.jp/cgi-open-bin/ctr\\_e/ctr\\_view.cgi?recptno=R000025102](https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000025102)

KP-100IT, the intrathecal formulation of recombinant human hepatocyte growth factor, is a novel investigational drug that has neurotrophic activities in the central nervous system. KRINGLE successfully completed open-label, dose-escalating Phase 1 study in ALS patients and confirmed safety and pharmacokinetics profiles of the intrathecal administration of KP-100IT. These clinical results were published in *The Journal of Clinical Pharmacology* 2019, 59(5) 677–687. Following the Phase 1 study, an investigator-initiated Phase 2 study was started by Professor Masashi Aoki, Department of Neurology in Tohoku University School of Medicine, on the basis of collaboration between KRINGLE and Tohoku University.

### ***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 including not only liver, but also kidneys, heart, lungs, nerve tissues and skin. Therapeutic effects of HGF administration in model animals of intractable diseases have been reported in many scientific papers, and expectations for HGF as a novel therapeutic agent for intractable diseases are increasing.

### ***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.

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

Daichika Hayata

Director, Pharmaceutical Development

Kringle Pharma, Inc.

☎ +81-72-641-8739

✉ [kpinfo@kringle-pharma.com](mailto:kpinfo@kringle-pharma.com)