Press release
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Update on the Investigator-initiated Phase 2 Study in Patients with ALS

Kringle Pharma, Inc. (Head office located in Osaka, Japan; President & CEO, Kiichi Adachi; "KRINGLE"), a late clinical-stage biopharmaceutical company, today announces that it has received the results of the investigator-initiated phase 2 clinical study evaluating its recombinant human HGF (KP-100IT) for the treatment of amyotrophic lateral sclerosis (ALS) from Tohoku University, located in Miyagi, Japan.

The study was a randomized, double-blind, placebo-controlled, phase 2 clinical study to evaluate the efficacy and safety of KP-100IT in a total of 46 ALS patients with Japan ALS Severity Classification of Grade 1 or 2, within 30 months of onset of the disease. KP-100IT (for 32 patients) or placebo (for 14 patients) was administered intrathecally once every two weeks, and the change in ALSFRS-R score at the 24-week treatment period was evaluated as a primary endpoint. As a result, there was no statistically significant difference between the KP-100IT group and the placebo group. No statistically significant differences were observed in the pre-specified secondary endpoints between the two groups. On the other hand, in the KP-100IT administered group, slowing of the disease progression was observed in some cases and further detailed analysis is required to interpret the results of this study. Regarding safety, the incidence of adverse events was similar between the KP-100IT and placebo groups, confirming that the intrathecal administration of KP-100IT was well-tolerated. KRINGLE will discuss with Tohoku University to determine the potential next step of development based on the results of further detailed analysis of the study.

About Amyotrophic Lateral Sclerosis (ALS)
ALS is an intractable neurodegenerative disease that gradually impairs motor function due to degeneration of motor neurons. In Japan, it is reported that approximately 10,000 patients are designated to have ALS. The causes of ALS are various, reportedly including genetic association or glutamate toxicity, but mostly unknown. The common symptom is muscle atrophy caused by motor neuron damage and loss, and therefore protection of motor neurons is considered beneficial for the therapeutic efficacy.

About Japan ALS Severity Classification
Severity of ALS is classified from Grade 1 (least severe) to Grade 5 (most severe) defined by Japan Ministry of Health, Labor and Welfare Specific Disease Research Group.

About ALS Functional Rating Scale-Revised (ALSFRS-R)
The ALSFRS-R measures 12 aspects of physical functions from one's daily life. Each function is scored from 4 (normal) to 0 (no ability), with a total score of maximum 48 to minimum 0.

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