Press release
24 July 2026

Kringle Pharma Advances the Registrational Program for Oremepermin Alfa in Japan with Initiation of Additional Phase 3 in Acute Spinal Cord Injury

Osaka, Japan – Kringle Pharma, Inc. (Tokyo Stock Exchange Growth: 4884, "KRINGLE"), a late-stage clinical biopharmaceutical company developing innovative therapies for rare and difficult-to-treat diseases, announced the initiation of an additional Phase 3 clinical study evaluating oremepermin alfa, recombinant human hepatocyte growth factor (HGF), for the treatment of patients with acute spinal cord injury (SCI) in Japan. Patient enrollment is expected to begin after site activation at participating study sites.

The additional Phase 3 study is a multicenter, open-label, single-arm clinical trial designed to evaluate the efficacy and safety of oremepermin alfa in patients with acute cervical SCI. A total of 10 patients are planned for enrollment across three national SCI hospitals in Japan. Eligible patients are adults aged 18 to 89 years who are diagnosed with AIS grade A cervical SCI and remain neurologically complete at 72 hours (±6 hours) following injury. Participants will receive 0.6 mg of oremepermin alfa administered intrathecally once weekly for five consecutive weeks. The primary endpoint is the proportion of patients whose neurological status improves to AIS grade C or better six months after treatment initiation.

Based on analyses of prior clinical studies and discussions with the PMDA, the Japanese regulatory agency, the additional Phase 3 study incorporates refined eligibility criteria to enrich for responders. Patients with severe structural spinal cord damage on magnetic resonance imaging (MRI), including spinal cord compression of 70% or greater and cases strongly suggestive of spinal cord transection, are excluded. By reducing heterogeneity among AIS grade A patients, the study aims to more accurately assess the therapeutic effects of oremepermin alfa in patients with retained recovery potential. For detailed information on the study design and eligibility criteria, please refer to the ClinicalTrials.gov listing at the following URL:
https://clinicaltrials.gov/study/NCT07722962

Acute SCI is a devastating neurological condition that can result in permanent motor, sensory, and autonomic dysfunction. Although advances in acute care and rehabilitation have improved outcomes, no widely established regenerative pharmacotherapy exists to restore neurological function, underscoring a substantial unmet medical need.

Kiichi Adachi, President and CEO of KRINGLE, commented:
"The initiation of this additional Phase 3 clinical trial marks a significant milestone in our mission to bring a regenerative treatment option to patients with acute SCI. We are committed to executing the study efficiently and to working closely with investigators and clinical sites to accelerate patient enrollment and advance oremepermin alfa toward commercialization in Japan. At the same time, we are actively pursuing global development opportunities and exploring pathways to expand the clinical development of oremepermin alfa beyond Japan, with the goal of making this innovative therapy available to patients worldwide."

About Oremepermin Alfa
Oremepermin alfa is the international nonproprietary name (INN) for recombinant human hepatocyte growth factor (HGF) developed by Kringle Pharma. Oremepermin alfa is a glycoprotein (molecular weight: approximately 84,000) consisting of 692 amino acid residues and is produced in CHO cells.

About Hepatocyte Growth Factor (HGF)

HGF, initially identified as an endogenous mitogen for mature hepatocytes, has demonstrated a wide array of biological functions, including mitogenic, motogenic, anti-apoptotic, morphogenic, anti-fibrotic, and angiogenic activities. It is crucial for the regeneration and protection of various organs. Importantly, HGF has shown neurotrophic effects and has been validated in animal models for its therapeutic potential in spinal cord injuries, as demonstrated by research conducted by Professors Hideyuki Okano and Masaya Nakamura at Keio University School of Medicine. Enthusiasm for HGF as a groundbreaking therapeutic agent for spinal cord injury continues to grow.

Meanwhile, a research team led by Professor Shigeru Hirano in the Department of Otolaryngology and Head and Neck Surgery at Kyoto Prefectural University of Medicine has investigated the anti-fibrotic effects of HGF and demonstrated its effectiveness in treating vocal cord scarring. HGF is also emerging as a promising therapeutic option for a range of fibrotic diseases.

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

Founded in December 2001, Kringle Pharma is a late-stage clinical biopharmaceutical company focused on developing innovative biologics based on HGF. Oremepermin alfa is currently in Phase 3 in Japan for the treatment of acute spinal cord injury and vocal cord scarring. Kringle's mission is to improve societal and global healthcare by advancing the research, development, and commercialization of HGF-based therapies for patients with incurable diseases. To accelerate the international development of oremepermin alfa, Kringle Pharma USA, Inc. was established in November 2025 as a U.S. subsidiary.

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