

Press release
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Kringle Pharma Announces IND Submission to the U.S. FDA for Oremepermin Alfa for the Treatment of 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 that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for oremepermin alfa, a recombinant human hepatocyte growth factor (HGF), to initiate a Phase 3 clinical trial in the U.S. for the treatment of acute spinal cord injury (SCI).

Oremepermin alfa is KRINGLE's proprietary recombinant human HGF protein therapeutic. In Japan, KRINGLE has completed Phase 1/2 and Phase 3 clinical trials in patients with acute SCI, generating extensive clinical data on its safety and efficacy in humans. KRINGLE is currently conducting an additional Phase 3 clinical trial in Japan to support a future regulatory submission. Oremepermin alfa has also received Orphan Drug Designation for the treatment of acute SCI in Japan, the U.S., and Europe.

Kiichi Adachi, President and CEO of KRINGLE, commented:

"Submitting this IND application marks a major step forward in the global development of oremepermin alfa and a significant milestone for KRINGLE. Building on the encouraging results of our extensive nonclinical and clinical studies in Japan, we are entering a new phase of development to advance oremepermin alfa toward regulatory approval in the U.S.

Having an active IND in the U.S. is an important achievement not only for advancing clinical development but also for expanding opportunities for strategic pharmaceutical partnerships and non-dilutive funding.

Driven by our mission to deliver innovative treatment options for patients with SCI worldwide, we remain committed to advancing the global development of oremepermin alfa toward regulatory approval and commercialization."

About Spinal Cord Injury

Traumatic spinal cord injury (SCI) is a debilitating condition caused by spinal cord damage from events such as motor vehicle accidents and falls, leading to impairment of motor, sensory, and autonomic functions. In the U.S., the annual incidence of traumatic SCI is estimated at approximately 54 cases per million population, corresponding to about 18,482 new cases each year. In addition, the prevalence of SCI, including individuals living with chronic disability, is estimated at approximately 311,560 people. Fewer than 1% of patients experience complete neurological recovery by the time of hospital discharge, highlighting the substantial unmet medical need that remains despite advances in supportive care and rehabilitation.

Source: National Spinal Cord Injury Statistical Center. Traumatic Spinal Cord Injury Facts and Figures at a Glance. 2026.

About Oremepermin Alfa

Oremepermin alfa is the international nonproprietary name (INN) for recombinant human hepatocyte growth factor (HGF) developed by Kringle Pharma. It 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.

Business Development, Investor, and Media Contact:

Matt Vogelhuber
President, US Head of Operations
Kringle Pharma USA, Inc.
Phone: 770-570-0641
Email: mvogelhuber@kringle-pharma.com

Kazuki Kaneshiro
Director, Corporate Strategy Office
Kringle Pharma, Inc.
Phone: +81-6-7653-6728
Email: kpinfo@kringle-pharma.com