Press release
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Completion of Patient Enrollment in Phase 3 Study of Oremepermin Alpha for the Treatment of Vocal Fold Scarring

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, today announced the successful completion of the last patient enrollment in a multicenter, randomized, placebo-controlled, double-blind, confirmatory Phase 3* study evaluating intracordal injection of oremepermin alfa, in patients with vocal fold scarring ("VFS") including sulcus vocalis.
*ClinicalTrials.gov ID：NCT05627648 https://www.clinicaltrials.gov/ct2/show/NCT05627648

KRINGLE has been developing oremepermin alfa therapeutics for various intractable fibrotic diseases, initially focusing on VFS. Following completion of an open-label, dose-escalation Phase 1/2 study demonstrating its safety and potential effectiveness in patients with VFS, KRINGLE advanced to this Phase 3 study assessing the efficacy and safety of oremepermin alfa in patients with VFS. Follow-up for the last enrolled patient and the announcement of the Phase 3 study's topline results are expected in 2027.

Kiichi Adachi, President & CEO of KRINGLE, stated, “VFS is a rare condition with no approved therapies, constituting a significant unmet medical need. Our development strategy is to initially commercialize oremepermin alfa for VFS and subsequently pursue expansion of the indication into broader fibrotic diseases such as pulmonary fibrosis, liver cirrhosis, myocardial infarction, and chronic renal failure. These fibrotic disorders collectively affect large patient populations and represent substantial market opportunities.”

The Phase 3 study has been supported by the Japan Agency for Medical Research and Development (AMED) through its CiCLE program (Project title: Clinical development of recombinant HGF protein for the treatment of refractory fibrosis).

About Oremepermin Alpha
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 Vocal Fold Scarring
Vocal fold scarring is a fibrotic disease that causes severe dysphonia. In patients with vocal fold scarring, fibrosis forms in the vocal fold mucosa due to inflammation or injury, hardening the mucosa and impairing the function of the vocal cords. Dysphonia makes daily communication difficult, leading to a significant deterioration in QOL (Quality of Life). No effective treatment has been established, and there are significant unmet medical needs for patients who suffer greatly. It is estimated that there are approximately 700,000 patients with vocal fold scarring worldwide**.
** Estimated by KRINGLE based on disease prevalence in Japan

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 at the Department of Otolaryngology and Head and Neck Surgery at Kyoto Prefectural University of Medicine has investigated the anti-fibrotic effects of HGF, demonstrating its effectiveness in treating vocal cord scarring. HGF is also emerging as a promising therapeutic option for various 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. Currently, oremepermin alfa is 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 US subsidiary.

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