



Press release
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Update on Progress of Phase III Clinical Study for the Treatment of Vocal Fold Scar: All Clinical Sites are Ready to Enroll Patients

Kringle Pharma, Inc. (Head office located in Osaka, Japan; President & CEO, Kiichi Adachi; “KRINGLE”), a late clinical-stage biopharmaceutical company, today provides an update on Phase III clinical trial confirming the safety and efficacy of KP-100LI, the intracordal formulation of recombinant human HGF, administered in patients with vocal fold scar. The study started enrolling patients in January this year at University Hospital, Kyoto Prefectural University of Medicine. Since then, the other four clinical sites have been fully activated, now being ready to recruit participants.

KRINGLE aims to develop and commercialize HGF as an innovative therapeutic agent for various fibrotic diseases, focused on vocal fold scar as the initial target indication. The Phase III study began in November 2022 at University Hospital, Kyoto Prefectural University of Medicine where the patient enrollment is ongoing, as announced in the News Releases dated November 24, 2022 and January 13, 2023. KRINGLE has completed the contracts and preparations with additional clinical trial sites. The study now starts recruiting patients across the four sites in Japan, Kurume University Hospital, Tohoku University Hospital, Kawasaki Medical School Hospital and Nihon University Hospital. KRINGLE will continue its efforts to advance the study and is committed to providing an innovative therapy for patients suffering from vocal fold scar as soon as possible.

The Phase III study has been supported by the Japan Agency for Medical Research and Development (AMED) as its CiCLE program (Project title: Clinical development of recombinant HGF protein for the treatment of refractory fibrosis). For additional information about the Phase III study, please visit the following websites:

- ClinicalTrials.gov ID: NCT05627648
<https://clinicaltrials.gov/ct2/show/NCT05627648>
- jRCT (Japan Registry of Clinical Trials) ID: jRCT2051220132
<https://jrct.niph.go.jp/en-latest-detail/jRCT2051220132>

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.

About Vocal Fold Scar

Vocal fold scar is a fibrotic disease which causes severe dysphonia. In patients with vocal fold scar, fibrosis is formed 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



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deterioration in QOL (Quality of Life). No effective treatment has been established and there are huge unmet medical needs for the patients who suffer greatly. It is estimated that there are approximately 10,000 patients with vocal fold scar in Japan¹⁾.

1) Koichi Tsunoda, “Research to formulate guidelines for establishment and standardization of diagnosis and treatment of vocal fold abnormalities” Research paper on epidemiology of intractable diseases, the Ministry of Health, Labour and Welfare of Japan. 2009.

About CiCLE (Cyclic Innovation for Clinical Empowerment)

CiCLE is a funding program operated by AMED to support medical research and development in the field of pharmaceuticals, medical devices, regenerative medicine products and medical technology. It aims to drive the creation of an environment that strongly promotes the fostering of open innovation through efforts of government, academia and the private sector.

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 conducts two Phase III clinical studies, which is the final stage of the drug development, in acute spinal cord injury and vocal fold scar among other target indications. KRINGLE has been a leading company to develop a pharmaceutical treatment for vocal fold scar. At present, we are the only company in the world who completed an early clinical development and has advanced to the Phase III stage in the indication. 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.

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