



Press release

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Kringle Pharma and Maruishi Pharmaceutical Enter into a Capital and Business Partnership for KP-100IT in Acute Spinal Cord Injury

Kringle Pharma, Inc. (Head office located in Ibaraki, Osaka; President & CEO, Kiichi Adachi; “KRINGLE”) today announces that it has entered into an agreement with Maruishi Pharmaceutical Co., Ltd. (Head office located in Osaka; President and Representative Director, Katsuhito Inoue; “MARUISHI”). After regulatory approval in Japan for KP-100IT, KRINGLE’s recombinant human hepatocyte growth factor, for the treatment of patients with acute spinal cord injury (SCI), MARUISHI will receive an exclusive sales and marketing license in Japan. In addition, MARUISHI will become an equity investor in KRINGLE.

KRINGLE completed the multicenter, randomized, double-blind, placebo-controlled Phase 1/2 of KP-100IT in subjects with acute SCI, and obtained positive safety and efficacy results. KP-100IT was designated as an orphan drug in Japan on the basis of the limited number of patients, a high unmet medical need and promising Phase 1/2 results in acute SCI. KRINGLE is currently conducting the multicenter, non-randomized, confirmatory Phase 3 trial in subjects with acute SCI. After the successful completion of this study, KRINGLE will apply for manufacturing and marketing approval in Japan. Upon regulatory approval, MARUISHI will have exclusive rights to market and promote KP-100IT for acute SCI in Japan. KRINGLE previously announced an alliance with Toho Holdings Co., Ltd., who will hold sole responsibility for the wholesale marketing and distribution of the KP-100IT in Japan.

Kiichi Adachi, Ph.D., President and CEO of KRINGLE, commented that “KP-100IT medicine is prescribed for SCI patients immediately after they are transported to emergency hospitals nationwide. As a specialty pharmaceutical company in the field of perioperative and emergency medicines, MARUISHI has a robust sales force that covers the majority of the emergency hospitals in Japan, making it an ideal partner to market and promote KP-100IT. In cooperation with MARUISHI, we are committed to maximizing the market value of KP-100IT while improving the quality of life for patients with acute spinal cord injury in Japan.”

About Hepatocyte Growth Factor (HGF)

HGF was originally found in Japan to be a mitogen for mature hepatocytes, and subsequent studies elucidated that HGF facilitates regeneration and protection of tissues damaged by injury and disease through its mitogenic, motogenic, and morphogenic properties as well as anti-apoptotic, anti-fibrotic and angiogenic activities. In the brain and nerve tissues, HGF exerts neurotrophic effects and enhances neurite outgrowth. The therapeutic effects of HGF on SCI and amyotrophic lateral sclerosis (ALS) have been demonstrated in animal models by Professors Hideyuki Okano and Masaya Nakamura at Keio University School of Medicine



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and Professor Masashi Aoki at Tohoku University, respectively. Based on these preclinical results, it is anticipated that HGF will be an effective and novel drug in the treatment of many incurable neuronal diseases.

About Spinal Cord Injury

Most spinal cord injuries result from some form of trauma, leading to a variety of painful and/or paralytic symptoms. The most frequent cause of injury is traffic accidents followed by falls from a height. Recently, due to the rise in the elderly population, falls as a cause is becoming increasingly common. Approximately 5,000 people suffer spinal cord injuries each year in Japan. Through appropriate and early initiation of treatment after the injury and specialized rehabilitation, some degree of functional recovery can be expected. However, complex and severe symptoms, including motor paralysis, muscular spasticity, sensory paralysis, dysfunction of internal organs (rectal and bladder disorder, thermoregulatory dysfunction, decreased visceral function, decreased respiratory function) often remain. For these reasons, therefore, there is a strong need for the development of a novel therapeutic for early interventional treatment in acute SCI patients.

About Maruishi Pharmaceutical Co., Ltd. <https://www.maruishi-pharm.co.jp/english/>

Maruishi Pharmaceutical was founded as a manufacturer of Japanese Pharmacopoeia drugs (namely, basic drugs) in 1888, the year following the establishment of the Japanese Pharmacopoeia. Today, Maruishi has grown into an R&D oriented, pharmaceutical company that is internationally recognized as a specialized pharma focused in the perioperative, antiseptics and disinfectants area. While Maruishi continues to focus on the existing area, Maruishi is expanding their targets into acute care medicine. Making use of the technology, knowledge, and know-how which Maruishi has cultivated over the 130 years of history, Maruishi will continue to contribute to healthcare not only in Japan but also in Asia and the rest of the world.

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

Kringle Pharma is a late-stage biopharmaceutical company established in December 2001 to develop novel biologics based on HGF. Currently, Kringle's clinical programs with recombinant human HGF are: 1) Phase 3 in acute spinal cord injury (ongoing), 2) investigator-initiated, double-blind, placebo-controlled Phase 2 in amyotrophic lateral sclerosis (ALS) (ongoing), 3) Phase 1a and 1b in acute kidney injury (completed), and 4) investigator-initiated Phase 1/2 in vocal fold scar (completed). Kringle's mission is to contribute to societal and global health through the continued research, development and commercialization of HGF for patients suffering from incurable diseases.

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