



Press release
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Kringle Pharma and Toho Holdings Enter into a Capital and Business Alliance 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 a capital and business alliance with Toho Holdings Co., Ltd. (Head office located in Tokyo; Chairman of the Board and Chief Executive Officer (CEO), Representative Director, Norio Hamada; “TOHO HOLDINGS”). After the recombinant human hepatocyte growth factor (KP-100IT) developed by KRINGLE for acute spinal cord injury (SCI), is approved for pharmaceutical manufacturing and marketing in Japan, TOHO HOLDINGS will take over the sole role for its domestic marketing, sales and distribution for acute SCI in Japan.

KRINGLE completed the multicenter randomized double-blind placebo-controlled Phase I/II 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 I/II results in acute SCI. KRINGLE is currently in discussions with the Japanese regulatory authority, PMDA, regarding a confirmatory study for its regulatory approval application, and plans to initiate the seminal Phase III clinical trial in the second half of 2020.

KP-100IT will be prescribed to patients transported to emergency hospitals nationwide during the acute phase of SCI. TOHO HOLDINGS has a leading pharmaceutical sales and distribution network that covers emergency hospitals nationwide, advanced drug storage and management capabilities, progressive information provisions to medical institutions as well as exceptional post-marketing surveillance systems. KRINGLE will continue the further development of KP-100IT in acute SCI with the aim of obtaining regulatory approval in Japan, and cooperating with TOHO HOLDINGS as a total solution provider with the goal of establishing a preeminent sales and distribution channel for KP-100IT 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 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.



Kringle
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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 Toho Holdings Co., Ltd. <https://www.tohohd.co.jp/en/>

Toho Holdings is a corporate group active in medical, nursing and healthcare fields, engaged in pharmaceutical wholesaling, dispensing pharmacy, manufacturing and sales of pharmaceuticals, and development and provision of customer support systems under the corporate slogan "Total Commitment to Good Health". Toho Holdings also proactively promotes initiatives for regional medical collaboration, nursing and home care.

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

Kringle Pharma is a clinical-stage biopharmaceutical company established in December 2001 to develop novel biologics based on HGF. Currently, Kringle's clinical programs with rhHGF are: 1) Phase I/II DBT in acute spinal cord injury (completed), 2) investigator-initiated Phase II DBT in ALS (ongoing), 3) Phase I in acute kidney injury (completed), and 4) investigator-initiated Phase I/II 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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