



Press release
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Kringle Awarded NIBIO R&D Promotion Grant for Clinical Development of Human Recombinant HGF for Neurological Disorders

Kringle Pharma, Inc. (Head office located in Toyonaka, Osaka; President & CEO: Kunio Iwatani, "KRINGLE") today announced that it has been awarded a three-year grant from the National Institute of Biomedical Innovation (Ibaraki, Osaka; "NIBIO") in Japan. KRINGLE has been undertaking clinical development of human recombinant hepatocyte growth factor (HGF) for acute renal failure and leg ulcer. The new R&D program to develop HGF-based therapy for neurological diseases, particularly amyotrophic lateral sclerosis "ALS" and spinal cord injury "SCI", has been approved for an NIBIO R&D Promotion Grant for fiscal year 2007. The allocated budget for the first year of funding is 80 million Japanese yen.

HGF, a potent mitogen for mature hepatocytes, was discovered, purified and molecularly cloned by Professor Toshikazu Nakamura of Osaka University, a founder and currently Scientific Advisor of KRINGLE. HGF is an endogenous organotrophic factor thought to play an important role in the repair and regeneration of various tissues and organs. HGF also possesses trophic effects on neuronal cells including motor neurons. ALS and SCI are incurable neurological diseases, both characterized by motor neuron death. In animal models of ALS and SCI, intrathecal administration of human recombinant HGF results in significant protective and therapeutic effects such as delayed disease progression, life prolongation, and improvement of motor function. HGF is therefore expected to be an innovative therapeutic agent for ALS and SCI, and potentially for other incurable neurological diseases. KRINGLE has successfully established a GMP-compliant method for manufacturing human recombinant HGF (see KRINGLE Press Release dated June 12, 2007). With the funding of the NIBIO grant, KRINGLE will conduct additional preclinical studies and GMP manufacturing of clinical quantities in order to commence a clinical trial at the earliest opportunity.

Kunio Iwatani said, "We are very pleased and honored to have been recognized by the NIBIO with the R&D Promotion Grant. It is of great significance in global healthcare for KRINGLE to pursue clinical development of recombinant HGF for ALS and SCI, serious diseases with unmet medical needs. This project is based on the academic collaborative research at Tohoku, Keio and Osaka Universities. Thus, it is also highly valuable in terms of accelerating translational clinical research in Japan."

About Kringle Pharma, Inc.

Kringle Pharma is a biopharmaceutical company established in 2001 to develop novel biologics based on HGF and NK4, both discovered by Professor Toshikazu Nakamura at Osaka University. Currently, Kringle's pipeline consists of human recombinant HGF for the treatment of 1) acute renal failure, 2) skin ulcers, and 3) CNS diseases, in addition to human recombinant NK4 and NK4 gene therapy as treatments for cancer. For more information, please refer to the company's website: www.kringle-pharma.com/en/index.html.

About the National Institute of Biomedical Innovation

The National Institute of Biomedical Innovation was established in April 2005. The institute was formed as part of the reorganization of laboratories and institutes under the jurisdiction of the Ministry of Health, Labour and Welfare. In 1995 the Ministry, in a process distinct from its regulatory and promotion functions, began to integrate organizations in order to promote the development of pharmaceuticals and medical devices. For more information, please refer to the Institute's website: www.nibio.go.jp/english/index.html.

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