



Press release
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Kringle Pharma Files IND Application to FDA to Conduct Studies on recombinant human HGF for the Treatment of ARF

Kringle Pharma, Inc. (Head office located in Toyonaka, Osaka; President & CEO: Kunio Iwatani, "KRINGLE"), which is undertaking clinical development of recombinant human hepatocyte growth factor (HGF) for acute renal failure (ARF), is proud to announce that it has filed an IND (Investigational New Drug) application to the U.S. Food and Drug Administration (FDA) on September 26, 2008. The Phase 1 clinical study of HGF for renal disease patients is expected to be initiated from the last quarter of this year upon approval of the application.

ARF is a disease caused by rapid decline of renal function resulting from such events as dehydration, shock, ingestion of toxic substances (including some drugs), surgery, renal ischemia, rapidly progressive glomerulonephritis and acute interstitial nephritis. The mortality rate for ARF is 50%, however, the only existing treatment for the disease is limited to symptomatic therapy due to a lack of effective pharmaceutical agents. It is estimated that approximately 700,000 patients suffer from ARF annually in the US, with 140,000 of those being treated in intensive-care unit (ICU) settings.

Nonclinical studies using animals have shown that supplementation therapy of recombinant human HGF protein has significant ability to suppress ARF and also to promote the regeneration function of the injured kidney. The safety of recombinant human HGF therapy in humans will be studied as part of the phase 1 clinical trial, then the efficacy of the therapy will be determined during phase 2 studies.

Kunio Iwatani stated: "There is a significant number of patients suffering from ARF because of the lack of pharmaceutical agents that offer a fundamental cure for the disease. KRINGLE's recombinant human HGF protein therapy has curative potential by suppressing ARF and promoting regenerative function of the injured kidney. As we are keen to offer such a medication to patients as quickly as possible, we will be accelerating its clinical development."

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 Emeritus Toshikazu Nakamura at Osaka University. Currently, Kringle's pipeline consists of human recombinant human HGF for the treatment of 1) acute renal failure, 2) skin ulcers, and 3) CNS diseases, in addition to recombinant human NK4 and NK4 gene drugs for cancer therapy. For more information, please refer to the company's website: www.kringle-pharma.com/en/index.html.

For more information, please contact:

Tomoya Shimojo, Director of Corporate Planning, Kringle Pharma, Inc.
Tel: +81 6 6831 3330
E-mail: info@kringle-pharma.com