



Press release  
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## **Kringle Pharma Achieved Permission to Conduct Phase 1 Clinical Studies on recombinant human HGF for the Treatment of ARF in US**

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 its IND (Investigational New Drug) application dated September 26, 2008 (refer our press release dated October 1, 2008) was permitted by FDA to initiate the phase 1 clinical study of HGF for ARF patients.

KRINGLE will commence the phase 1 clinical study of HGF for ARF patients in US within this year.

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 "I am extremely proud that KRINGLE has achieved a permission from FDA to initiate phase 1 clinical study of HGF for ARF patients. There are a significant number of patients suffering from ARF because of the lack of pharmaceutical agents that offer a fundamental cure for the disease. As we are keen to offer such a medication to patients as quickly as possible, we will be accelerating its clinical development following FDA's permission."

### ***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](http://www.kringle-pharma.com/en/index.html).*

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