



Kringle
Pharma

Press release
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Kringle Pharma Finishes its Phase 1a Clinical Trial of Recombinant Human HGF for Treatment of Renal Disease

Kringle Pharma, Inc. (Head office located in Toyonaka, Osaka; President & CEO: Kunio Iwatani, “KRINGLE”) is pleased to announce that it has successfully finished both the dosing and primary safety evaluation in a phase 1a clinical trial of recombinant human hepatocyte growth factor (rhHGF) for US patients with renal disease. This trial was designed as the basis of clinical development of rhHGF for acute renal failure (ARF).

This phase 1a study was a single dose study intended to assess both safety and pharmacokinetics of rhHGF in patients with chronic kidney disease. Using the outcomes of the study, Kringle will be consulting with the U.S. Food and Drug Administration (FDA) to initiate a phase 1b study to examine the safety and pharmacokinetics of multiple doses of rhHGF.

To accelerate the approval process, Kringle applied to the FDA for Fast Track designation of its ARF therapy program, which was granted by the FDA this month. Fast Track designation is designed to facilitate development and expedite review of a drug candidate that treats a serious or life-threatening condition and addresses an unmet medical need. Kringle has now met FDA requirements in this regard and can benefit from various incentives provided by the FDA to facilitate the approval procedure.

ARF is a disease caused by a rapid decline in 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 as high as 50% because the condition often leads to severe complications in other organs; however, the only current 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 United States, with 140,000 of those being treated in intensive-care unit (ICU) settings.

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 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.

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