



Press release
3 December 2008

Kringle Pharma Initiated a Phase 2 Clinical Trial in Norway on ChronSeal®, a Recombinant Human HGF-Based Therapy for the Treatment of Skin Ulcers.

Kringle Pharma, Inc. (Head office located in Toyonaka, Osaka; President & CEO: Kunio Iwatani, "KRINGLE") proudly announces it has initiated a phase 2 clinical trial of ChronSeal®, a novel wound healing therapy using recombinant human hepatocyte growth factor (HGF) for venous leg ulcers in Norway.

A clinical trial application for the phase 2 study was submitted to the Norwegian Medicines Agency (NoMA) on August 4, 2008. It was approved by NoMA to conduct the study on October 3, and the recruitment of the study subjects has started from November.

A therapeutic potential of HGF against skin ulcers was previously observed in the investigational pilot human studies which undertook at Linköping University Hospital, Sweden. The upcoming phase 2 study in Norway will evaluate the therapeutic efficacy as well as safety and tolerability of ChronSeal®. The phase 2 trial is designed as a randomized, double-blind, and vehicle controlled study for the subjects with venous leg ulcers. Detail of the clinical trial is released by US Food and Drug Administration (FDA) database ClinicalTrials.gov., which is found at below URL.

www.clinicaltrials.gov/ct2/show/NCT00797706?term=Kringle&rank=1

The clinical trial application was also submitted to the Medical Products Agency (MPA) in Sweden and is still pending.

Kunio Iwatani stated "I am extremely proud that KRINGLE has initiated a phase 2 clinical study of HGF for venous leg ulcers in Norway. Although it was based on the academic pilot studies, the therapeutic effects of HGF against venous leg ulcers are obvious and promising. Through this phase 2 clinical trial in Norway, KRINGLE is expecting to achieve proof of concept (POC) of HGF as a pharmaceutical product."

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.

About ChronSeal®

ChronSeal® is a topical application therapy, having HGF as a main active pharmaceutical ingredient, for chronic leg wounds, a rapidly increasing problem among the elderly population of the World. In cooperation with Swedish partner Tripep AB, a new formulation has been developed that enables the use of ChronSeal® without it being combined with antibiotics. An application for a patent pertaining to an antibiotic-free formulation of ChronSeal® was filed in the US in January 2008.

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