



Kringle
Pharma

Press release
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Kringle Pharma Commences a Phase I/II Clinical Trial in Sweden 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") is proud to announce that the clinical trial application of ChronSeal[®] to the Swedish authority, Medical Products Agency (MPA), dated 23 December 2008 was approved on 23 January 2009. Having its approval granted by the authority, KRINGLE will conduct a phase I/II clinical trial of ChronSeal[®] in Sweden.

ChronSeal[®] is a topical application therapy having recombinant human hepatocyte growth factor (HGF) as a main effective pharmaceutical ingredient. Its clinical trial has already been initiated in Norway from November 2008 (refer to our press release dated 3 December 2008). Regulatory approval granted by MPA allows KRINGLE to commence a multi-national clinical trial of ChronSeal[®] in two Scandinavian countries.

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 I/II study in Sweden will evaluate the therapeutic efficacy of ChronSeal[®]. The phase I/II trial is designed as a randomized, double-blind, and vehicle controlled study for the subjects with venous leg ulcers. For more details, please refer to the US Food and Drug Administration (FDA) database ClinicalTrials.gov with identifier No. NCT00797706.

Kunio Iwatani stated "I have no doubt that the clinical development of ChronSeal[®] will increase its tempo by having additional clinical sites in Sweden, besides Norwegian sites. KRINGLE will make its endeavor towards proof of concept (POC) of HGF as pharmaceutical product through steady clinical operation in two Scandinavian countries."

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.

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.

For more information, please contact:

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