

Kringle Pharma, Inc.

Pushing a paradigm shift in drug development with Hepatocyte Growth Factor(HGF)

www.kringle-pharma.com/en

Kringle Pharma, Inc. 18F Senri Asahi Hankyu Bldg. 1-5-3 Shinsenri-Higashimachi, Toyonaka Osaka 560-0082 JAPAN	Founded in No. of employees State of Ownership Primary stock exchange	2001 18 private N/A
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June 2009: Kringle Pharma was founded by the scientists who discovered HGF (Hepatocyte Growth Factor) and its intramolecular fragment NK4. The company is focusing on drug development with these molecules possessing potent therapeutic values. Kringle has, for the first time in the world, industrialized recombinant human HGF in accordance with GLP and GMP requirements. Venture Valuation (VV) interviewed Mr. Kunio Iwatani, President and CEO.



VV:

Would you please describe your business and its strengths?

Iwatani:

We develop and market novel therapeutics based on HGF and NK4. HGF has power to regenerate and heal not limited to liver tissue but kidney, lung, skin, nervous and cardiovascular tissues. Also HGF has antifibrotic activity that no other growth factors demonstrate. This means HGF has high potential to become a therapeutic agent for intractable fibrotic diseases such as liver cirrhosis, arteriosclerosis, cardiomyopathy, and so on. Up to now there is no specific therapy for them.

NK4, HGF intramolecular fragment, is a bi-functional molecule. It functions as HGF antagonist as well as an angiogenesis inhibitor. Because NK4 suppresses the action of angiogenetic factors, it is a good candidate for the therapy of various cancers.

Currently, we have five projects in pipeline: three with HGF and two with NK4. (see chart below). Two of them are in clinical development. Our flagship is the Venous Leg Ulcers Project with ChronSeal®, a gel containing recombinant human HGF for the treatment of chronic skin wounds. In collaboration with Trepep AB, a Swedish biotech research company, Phase I/II is in progress at 11 medical facilities in Sweden and Norway. We were able to skip Phase I with healthy volunteers because investigational human studies had been already conducted at Linköping University Hospital in Sweden.

R&D Pipeline



Project	Target disease	Pre-clinical	Clinical Development			Comments
			P I	P II	P III	
HGF	Chronic Skin Ulcers / EU (Venous Leg Ulcers)					Option agreement with Maruho
	Acute Renal Failure / US					Collaboration with The Rogosin Institute, NY
	Amyotrophic Lateral Sclerosis and Spinal Cord Injury / Japan					Collaboration with Keio and Tohoku Universities
NK4	Solid Tumors					First target to be glioma
	Esophagus Cancer (Gene Therapy)		Investigational study			In preparation for human study

◆ Seeking pharmaceutical companies interested in in-license/co-development of novel medical seeds.

There are approximately eight million patients, particularly among senior people, suffering from chronic leg wounds in Europe and the U.S. The older the population, the more crucial it is to provide an efficacious cure.

The other project in clinical development is the Acute Renal Failure Project. Phase Ia study results are expected by the end of August this year in the U.S. We are glad to work with the Rogosin Institute in New York City, one of the best medical institutions specializing in kidney disease including dialysis and transplantation.

The other three projects are in preclinical development: amyotrophic lateral sclerosis and spinal cord injury, solid tumors, and esophagus cancer.

Our strengths are:

- Comprehensive patent portfolio. This is rooted in the lifelong researches of Prof. Toshikazu Nakamura, the acclaimed scientist who discovered HGF, and one of Kringle's founders;
- Know-how of industrializing the process of recombinant human HGF. We are the exclusive supplier in the world; and global collaboration network with prominent medical and scientific professionals.

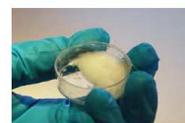
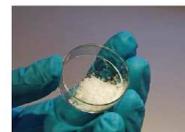
VV:

What are your objectives in the future?

Iwatani:

We are focusing on establishing positive results sometime next year from Phase II proof-of-concept trial of ChronSeal® cream (see photo below). We hope to blaze a trail to a new class of treatment that will combat chronic leg wounds.

ChronSeal® A Novel Formulation for Topical Application



Kringle filed a patent application in the US, January 2008.

Since the number of patients is larger in Europe than other parts of the



world, we established our subsidiary Kringle Pharma Europe AB in Stockholm, Sweden last year to open up licensing opportunities.

Another objective is to go public next year. Raising capital is an essential factor in order to strengthen R&D and business development.

VV: What opportunities are you exploring?

Iwatani: We are exploring the opportunity to partner with major pharmaceutical companies, especially those interested in niche-buster products.

In terms of scientific opportunity, HGF creates multiple possibilities to develop various therapeutic agents. The binding of HGF to its single receptor c-Met exerts multiple biological actions involved in cell proliferation, migration, morphogenesis, apoptosis, and breakdown of extracellular matrix.

VV: How do you differentiate from your competitors and position your company?

Iwatani: Our know-how of recombinant human HGF is the major differentiator. Another differentiating factor is that HGF has antifibrotic activity that no other growth factors demonstrate. We are well positioned to develop therapy for fibrotic diseases for which there are no therapies now.

VV Comments after the Interview:

The successful launch of its first product ChronSeal® cream will build up Kringle's corporate value in the world market. According to Tripep AB, "chronic leg ulcers represent over 40% of the market for active wound care products, a market that has had annual growth of over 10% over the last decade.

The estimated global market value of active wound-healing products was US\$1.7 billion in 2005, and sector analysts estimate it at US\$3 billion in 2011." The market segment that ChronSeal® is positioned in is expected to be around US\$1.2 billion in a few years.

Kringle has great potential to become a global leader of HGF/NK4 based therapies by managing aggressive fundraising and partnering in the international arena. It is worth observing how the company operates its business and corporate development aligned with its growth strategy.

Contact

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