₩ M3, Inc.

# Capital Alliance with Kringle Pharma, Inc. ~ 7P Initiative: Development of Therapeutic Drugs for Spinal Cord Injury ~

M3, Inc. (Headquarters: Tokyo, Japan; CEO: Itaru Tanimura; URL: <u>https://corporate.m3.com/</u>; "M3" below) has announced capital participation to Kringle Pharma, Inc. (Headquarters: Osaka, Japan; President & CEO: Kiichi Adachi; URL: <u>http://www.kringle-pharma.com/</u>; "Kringle Pharma" below) as the first investment for M3's CVC fund "1P1Y Fund," in conjunction with "7P Projects" initiatives.

#### 1. Background

M3 operates m3.com, a specialized web portal for medical professionals that delivers healthcare related information to its 280,000+ physician members in Japan, and offers marketing and clinical trial services. Recent business expansion have been in areas such as AI diagnostic tool development, genome diagnostics provision, and stroke rehabilitation centers, no longer limited to pharmaceutical marketing. "7P Projects" aim to integrate such businesses in order to provide holistic solutions for multiple issues within individual therapeutic areas. Furthermore, presence outside of Japan include the U.S., U.K., France, China, Korea and India, with aggressive business expansion overseas that has amassed over 5.8 million physicians as members across our global platforms, allowing provision of a wide range of services.

Kringle Pharma is a venture company launched by Osaka University with strength in R&D of HGF<sup>\*1</sup>-based therapeutic drugs for intractable diseases with no radical treatments, and has been funded by public institutions such as AMED<sup>\*2</sup> and JST<sup>\*3</sup>,. They have also been awarded with the Japan Bio-Venture Award in 2009 (past winners include PeptiDream Inc. and SanBio Co., Ltd.) HGF is a regenerative repair factor in the body, and is expected to become breakthrough treatments for various diseases. Kringle Pharma has accumulated HGF-related patents as well as valuable expertise on large-scale manufacturing of pharma-grade<sup>\*4</sup> HGF recombinant protein<sup>\*5</sup>, and focuses on domestic clinical trials for intractable neurological diseases such as acute injury of the spinal cord and amyotrophic lateral sclerosis (ALS).

Spinal cord injuries are mainly caused by traffic accidents and accidental falls, including falls from higher altitudes. In recent years, injuries from falls have been increasing due to an aging population, causing spinal cord injury patients to increase by roughly 5,000 annually. There is currently no drug to treat spinal cord injury in the acute phase, thus the demand for a new drug is very high. Kringle Pharma's Phase I / II clinical trials for acute spinal cord injury have confirmed the safety and efficacy of the HGF-based drug. Due to high medical needs, the drug has been approved as an orphan drug by the Ministry of Health, Labor and Welfare as of September 12, 2019. To reach patients in need as soon as possible, Kringle Pharma is preparing for its Phase III trial, aiming to expedite the launch of the drug.

- \*1 Hepatocyte Growth Factor
  \*2 Japan Agency for Medical Research and Development
  \*3 Japan Science and Technology Agency
  \*4 Protein produced from host cells transfected with human HGF gene using genetic recombination techniques
  \*5 GMP(Good Manufacturing Practice) grade
- < Anticipated Therapy Areas for Potential Clinical Application of HGF<sup>\*6</sup> >

Organ	Disease Name (Blue letters: under development)
Neural	Spinal cord injury, Amyotrophic Lateral Sclerosis (ALS), cerebral infarction
Kidney	Acute renal failure, chronic renal failure, renal transplant, diabetic nephropathy
Liver	Acute hepatitis, fulminant hepatitis, cirrhosis, biliary atresia, fatty liver, liver transplantation
Lung	Acute pneumonia, pulmonary fibrosis, lung transplantation
Circulatory	Vascular disorders (atherosclerosis obliterans, prevention of vascular restenosis, etc.), myocardial infarction, dilated cardiomyopathy
Others	Skin ulcer, vocal fold scar

\*6 Not approved as of March 2020

## < Current Development Pipeline >

Disease	Development Phase	Country
Acute spinal cord injury	Phase III study in preparation Designated as orphan drug	Japan
Amyotrophic Lateral Sclerosis (ALS)	Phase II study (doctor- initiated clinical trial) ongoing	Japan
Vocal Cord Scar	Phase I / II study (doctor- initiated clinical trial) completed	Japan
Acute Renal Failure	Phase I study completed	US

### 2. Synergy Effect

M3 plans to address spinal cord injury under its 7P Projects initiatives, which are initiatives that aims to provide solutions for multiple issues within therapeutic areas by combining various services that extend beyond pharmaceutical marketing. In order to expedite its market launch, M3 will utilize M3 Group's know-how in R&D to offer regulatory consult, as well as implement digitalized clinical development services such as "Mr. Finder" to expedite recruitment of patients with acute phase of spinal cord injury in future trials.

Upon launch of Kringle Pharma's drug, M3 Group's services will be offered as solutions to various issues surrounding spinal cord injury, including "MR-kun family" marketing support services for promotion of appropriate drug usage, and "Y's" rehabilitation services for provision of optimal aftercare.



#### <Company Overview>

Name	Kringle Pharma, K.K.
Established	December, 2001
Headquarters	7-7-15 Asagi Saito Ibaraki City, Osaka
CEO	Kiichi Adachi
Nature of Business	Research & development of new bio-pharmaceuticals using
	HGF (pharmaceuticals for regenerative medicine)