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Company Name:	HEALIOS K.K.
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Notice of Selection for NEDO Public Call Project: 'Verification and Validation of Safety Toward Social Implementation of Japanese Medical-Specialized LLM'
- Pilot Program for Post-Marketing Study of a Treatment for Acute Ischemic Stroke –

HEALIOS K.K. ("Healios") is pleased to announce that Healios has been selected as a co-implementing partner for the project titled "Verification and Validation of Safety Toward Social Implementation of Japanese Medical-Specialized LLM," publicly solicited by NEDO (the New Energy and Industrial Technology Development Organization). This project (hereinafter referred to as the "Project") supports the development of treatments for acute ischemic stroke.

Call for Proposals: "Verification and Validation of Safety Toward Social Implementation of Japanese Medical-Specialized LLM" (only in Japanese)
Project Title: Verification and Validation of Safety Toward Social Implementation of Japanese Medical-Specialized LLM
Lead Organization: SAKURA internet Inc.
Project Period: The year 2025 (one-year period)

1. Background and Overview of Healios' Participation in the Project
Under Japan's conditional and time-limited approval system for regenerative medicine products, applicants are required to conduct post-marketing clinical studies or equivalent investigations (hereinafter referred to as "Post-Marketing Studies") within seven years of receiving conditional approval, in order to verify the product's safety and efficacy and apply for full marketing approval. However, in the case of urgent and lethal diseases, such as acute ischemic stroke, it is difficult to conduct Post-Marketing Studies because the patient's condition often changes rapidly, prompt treatment is prioritized, and it is difficult to manage compared to normal clinical trials, such as screening of enrolled patients.

Meanwhile, the rapid advancement of large language model (LLM) technology offers the potential to build a new environment for verifying safety and efficacy by organically linking clinical record data, particularly electronic medical records, which are accumulated daily under Japan's universal health insurance system.

Against this background, Healios is participating in the sub-project titled "Construction of a Registry Linked to Electronic Medical Records for Drug Discovery". The objective is to develop a system that automatically collects data to confirm the safety and efficacy of post-marketed drugs using LLM technology, and to accumulate real-world data from marketed drugs using the developed system. In addition, Healios will collaborate on the demonstration project for Post-Marketing Studies for the treatment of acute ischemic stroke.

Several organizations are scheduled to participate in the project as co-implementing partners, including Kyushu University and The University of Tokyo, along with multiple medical institutions, research organizations, and companies. Kyushu University has long maintained the Fukuoka Stroke Registry (FSR), a multi-institutional stroke database collecting clinical data on stroke patients. Drawing on this experience, Kyushu University will propose survey items and assist in designing the automated data collection system for post-marketed drugs. The Matsuo and Iwasawa Laboratory at The University of Tokyo will be responsible for developing and examining methods for extracting medical data using the LLM. Healios will focus primarily on the development of regenerative medicine products and the implementation of Post-Marketing Studies, specifically targeting acute ischemic stroke.

2. Future Outlook

This matter has no impact on our consolidated financial results of the fiscal year ending December 31, 2025. We will promptly announce any matters that should be disclosed in the future.

About Healios:

Healios K.K. is Japan's leading clinical stage biotechnology company harnessing the potential of stem cells for regenerative medicine. It aims to offer new therapies for patients suffering from diseases without effective treatment options. Healios is a pioneer in the development of regenerative medicines in Japan and owns proprietary, global platforms utilizing both somatic stem cells and iPS cells.

In the somatic stem cell field, Healios is developing invimestrocel (HLCM051), a proprietary cell product comprised of multipotent adult progenitor cells ("MAPCs") derived from the bone marrow of healthy adult donors. Invimestrocel has been shown to exhibit powerful anti-inflammatory and immunomodulatory properties with applicability in a range of disease states, has been tested in hundreds of patients in late stage clinical trials, is manufactured consistently at scale in 3D bioreactors, and has demonstrated both safety and suggested efficacy in hundreds of patients across multiple indications. Healios is seeking to advance invimestrocel on a global basis for ischemic stroke, ARDS, and trauma.

In the iPSC regenerative medicine field, Healios is developing HLCN061, a next generation NK cell treatment for solid tumors that has been functionally enhanced through gene-editing. These cells have demonstrated robust anti-tumor efficacy in animal models, benefit from a scalable 3D bioreactor manufacturing process, and are currently being prepared for initial human testing in collaboration with Akatsuki Therapeutics. The company has also established a proprietary, gene-edited "universal donor" induced pluripotent stem cell line to develop next generation regenerative treatments in immuno-oncology, ophthalmology, liver diseases, and other areas of severe unmet medical need.

Healios was established in 2011 and has been listed on the Tokyo Stock Exchange since 2015 (TSE Growth: 4593). https://www.healios.co.jp/en