Press Release



SHIONOGI Announces a Commercialization Agreement with SUSMED for a Digital Therapeutic App for Insomnia

OSAKA, Japan, December, 27, 2021 - Shionogi & Co., Ltd. (Headquarters: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced Shionogi entered into a commercialization agreement with SUSMED Co., Ltd. (Headquarters: Chuo-ku, Tokyo, President and CEO: Taro Ueno; hereafter "SUSMED"), regarding a digital therapeutic application for insomnia (hereinafter "this app").

This app is under development by SUSMED. In a Phase 3 trial in Japan, this app showed a statistically significant improvement in the Athens insomnia scale (an index of insomnia severity), the primary endpoint, compared to the control (sham) group. Based on the results of this trial, SUSMED plans to submit a new drug application for this digital therapeutic app for insomnia.

Under this agreement, Shionogi will acquire the exclusive marketing rights for this app in Japan. Shionogi will pay SUSMED up to 4.7 billion yen, including an upfront payment upon conclusion of the contract and development milestones. In addition, Shionogi will pay SUSMED royalties on product sales.

In the future, the strengths of both companies will be applied to develop and provide new healthcare solutions, including joint development of further digital therapeutic apps.

Shionogi is pursuing its vision looking toward 2030, "Building Innovation Platforms to Shape the Future of Healthcare" and pursuing transformation from a traditional "drug discovery-type pharmaceutical company" to a "HaaS company" that provides healthcare services. In parallel with refining the strengths we have cultivated as a drug discovery-type pharmaceutical company, Shionogi will strengthen our efforts to create new HaaS products and approaches, including through collaboration with external partners, and continue to provide new value in addressing the needs of patients and society.

*The "sham" app is similar but does not include the core digital therapeutic functionality.

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new

^{**} HaaS; Healthcare as a Service: Providing a range of healthcare services in line with customer needs, rather than only supplying pharmaceuticals.

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information, future events or otherwise.

For Further Information, Contact:

SHIONOGI Website Inquiry Form: https://www.shionogi.com/global/en/contact.html

About SUSMED

SUSMED is a research and development company that promotes digital medical care, and is working on the development of digital therapeutic apps. In addition, the company have patented technologies such as blockchain technology that leads to efficient clinical development trials and AI automatic analysis technology that is expected to improve the efficiency of data analysis and reduce costs. The company develops and provides clinical development support systems that utilize these technologies.