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Keio University School of Medicine
Sumitomo Pharma Co., Ltd.
i2medical LLC

MHLW Grants Priority Review to Support Program for Screening of Depression / Rating of Severity “SWIFT” (tentative name) as First Software as a Medical Device (SaMD)

A research group at Keio University, Sumitomo Pharma Co., Ltd. (Head Office: Osaka; Representative Director, President and CEO: Hiroshi Nomura), and i2medical LLC (Head of Development: Kuo-ching Liang) announced today that the Support Program for Screening of Depression / Rating of Severity, or “SWIFT” (tentative name, hereinafter “this product”), has been granted priority review by the Ministry of Health, Labour and Welfare (MHLW) as Japan’s first Software as a Medical Device (SaMD). The group was led by Keio University School of Medicine Project Professor Taishiro Kishimoto at the Hills Joint Research Laboratory for Future Preventive Medicine and Wellness together with Sumitomo Pharma Co., Ltd., and i2medical LLC, who have been developing this product for practical use.

This product is designed to detect depressive episodes¹ caused by depression or bipolar disorder and help rate the severity of the disease by analyzing patients’ vital signs and activity data collected from wearable devices. It would provide estimated results on the likelihood of depressive episodes per the global diagnostic criteria for mental disorders, the “Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition” (DSM-5), and the estimated scores of the Hamilton Depression Rating Scale.² Ongoing research aims to develop a medical device to provide information that would serve as evaluation material for physicians to make a diagnosis.

Sumitomo Pharma Co., Ltd. will proceed with the clinical development of this product within three years and aims to obtain early approval. Please note that the development of this product is supported by the Japan Agency for Medical Research and Development (AMED) for its “Research project for medical-engineering collaboration and implementation of artificial intelligence.”

¹ Depressive episode: A condition with symptoms such as depressed mood, diminished interest/joy, decreased appetite, insomnia, fatigue, a decline in energy, and impaired ability to think/concentrate. Persistent depressive episodes lead to a diagnosis of depression.

² Hamilton Depression Rating Scale: A scale for rating depression severity using 17 items

(Reference)

About the priority review system for SaMD products

This system was introduced on a trial basis by the MHLW in 2022 to prioritize the review of SaMD products that meet certain requirements, including innovativeness, usefulness, and the intention to develop the product and receive approval in Japan before expanding to other countries. The public application process began in September 2022.

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Contact for presentation materials

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Source of this release

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