

Ai-BrainScience Secures SaMD Approval in Philippines, for AiBS-01 as Dementia Screening Application

Ai-BrainScience Inc (Head Office: Osaka, CEO: Kentaro Takamura Ph.D., “the company/we” hereof) is pleased to announce that its product, AiBS-01, has received premarket approval as a Software as a Medical Device (SaMD) from the Food and Drug Administration Philippines.

We are actively expanding our business in the Asian market. This approval makes Philippines the fourth country, to approve AiBS-01. Moving forward, we will establish a sales infrastructure in preparation for the product launch, including collaboration with distribution partners.

Overview of AiBS-01

AiBS-01 is a Software as a Medical Device (SaMD) designed for use with the Apple iPad. It provides a 3-minute automatic assessment based on the patient’s gaze patterns on the screen. This approach eliminates the need for reliance on the physician’s expertise, enabling a more objective and quantitative evaluation.

Cognitive function tests, both domestically and internationally, often rely on screening methods such as the MMSE (Mini-Mental State Examination), which typically require around 20 minutes to administer^{*1}. These tests also demand specialized knowledge and experience from the examiner and can impose significant psychological burden on the examinee. It has been reported that approximately 70% of examinees experience distress during the testing process^{*2}. As a result, there is a growing demand for simpler, more objective methods of assessment. We hope that AiBS-01 will expand the options available for cognitive testing, helping to address current challenges both in Japan and abroad, and contributing to the early detection of dementia.

Country of approval for AiBS-01

		Approval Date	Distributor
1	Japan (Brand Name : MIREVO®)	October 2023	Otsuka Pharmaceutical Inc.
2	Indonesia	August 2024	TBD
3	Malaysia	October 2024	TBD
4	Philippines	January 2025	TBD

*1: Haubois et al. BMC Geriatrics 2011, 11:59

*2: Self-Reported Distress After Cognitive Testing In Patients With Alzheimer's Disease, August 2008

<Contact>

Ai-BrainScience Inc.

TEL : +81-3-6272-6744

e-Mail : info@ai-brainscience.co.jp

URL : <https://www.ai-brainscience.co.jp/en/>