

## **Ai-BrainScience Secures SaMD Approval in Malaysia, Following Indonesia, 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 Ministry of Health, Medical Device Authority in Malaysia, following its approval in Indonesia.

We are actively expanding our business and plan to launch AiBS-01 in the Asian market. This approval makes Malaysia the third country, after Japan and Indonesia, 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<sup>\*1</sup>. 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<sup>\*2</sup>. 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	<b>Japan</b> (Brand Name : MIREVO®)	October 2023	Otsuka Pharmaceutical Inc.
2	<b>Indonesia</b>	August 2024	TBD
3	<b>Malaysia</b>	October 2024	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

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