Ai-BrainScience Inc. 16th February 2025

Ai-BrainScience Achieves SaMD Registration with FDA in the United States of America for AiBS-01 as a 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 been successfully registered as a Software as a Medical Device (SaMD) from the U.S. Food and Drug Administration (FDA).

We are actively expanding the international presence of AiBS-01, and its recent registration in the United States marks the fourth country following the Philippine. Moving forward, we will continue to build our sales infrastructure in preparation for market 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.

*1: Haubois et al. BMC Geriatrics 2011, 11:59
*2: Self-Reported Distress After Cognitive Testing In Patients With Alzheimer's Disease, August 2008

Country of approval/registration for AiBS-01

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

FDA(Food and Drug Administration):
An organization that implements necessary measures and conducts research to ensure the efficacy and safety of pharmaceuticals, medical devices, and other related products, in order to protect public health. When exporting medical devices to the United States, notification and/or approval applications to this authority are required.

SaMD(Software as a Medical Device):
A software program intended for use as a medical device, which may pose a risk to the life or health of patients (or users) if it does not function as intended. Prior approval or registration with the relevant regulatory authority is required before it can be made available.

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