Ai-BrainScience Inc. 19th September 2025

Ai-BrainScience Receives TGA Approval in Australia for AiBS-01 as a Software as a Medical Device (SaMD) for Dementia Screening

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 regulatory approval from the Therapeutic Goods Administration (TGA) in Australia as a Software as a Medical Device (SaMD). It has also been included in the Australian Register of Therapeutic Goods (ARTG).

AiBS-01 continues to expand its international footprint, with recent approval and registration in Australia marking the fifth country outside Japan. We are now accelerating preparations for the market launch, including strengthening our sales infrastructure and partnering with local distributors.

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
6	**Australia**	September 2025	Approval	TBD

TGA (Therapeutic Goods Administration)
The Australian regulatory authority under the Department of Health, responsible for the oversight of medicines and medical devices in Australia.

ARTG (Australian Register of Therapeutic Goods)
A registration system managed by the TGA. Medical devices sold in Australia must be evaluated for safety and performance before being registered in the ARTG.

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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