To whom it may concern:

February 7, 2025

Company name:	ExaWizards Inc.
Name of representative:	Makoto Haruta, Representative Director and President (TSE Code No.4259)
Inquiries:	Tomoaki Maekawa, Executive Officer Corporate Management Head of Function

Notice on Consensus on Priority Review Designation for Consolidated Subsidiary's AI Medical Device (SaMD) under Innovative Programmed Medical Devices System

ExaWizards Inc. (hereinafter, “the Company”), announced that an AI medical device that diagnoses dementia through conversational speech (hereinafter, “the Product”), being developed by its wholly owned consolidated subsidiary, ExaMD Inc. (hereinafter, “ExaMD”) gained consensus on designating as a priority review product for programmed medical devices (SaMD: Software as Medical Device) by the Japanese Ministry of Health, Labor and Welfare on February 6, 2025.

1. Overview

For further information, please refer to the Appendix.

2. Impact to Consolidated Results

The Company is currently conducting a detailed analysis of the impact on future business development and performance. The Company will promptly disclose any significant impact as soon as it becomes known.

(Appendix)

News Release

February 7, 2025
ExaWizards Inc.
(TSE Code No.4259)
ExaMD Inc.

ExaWizards' Wholly Owned Subsidary, ExaMD AI-Powered Dementia Diagnosis App Using Conversational Audio Gained Consensus on Priority Review Designation under Innovative Medical Device Program

~Simple smartphone app that takes a minute to use, aiming for world-first approval as a diagnostic medical device ~

We, ExaWizards Inc. (Minato-ku, Tokyo, Representative Director & President: Makoto Haruta; hereinafter, "ExaWizards") is pleased to announce that an AI medical device that diagnoses dementia through conversational speech (hereinafter, "the Product") being developed by our wholly owned subsidiary, ExaMD Inc. (Minato-ku, Tokyo, Representative Director: Koji Hazama; hereinafter, "ExaMD") gained consensus on designating as a priority review product for programmed medical devices (SaMD: Software as Medical Device) by the Japanese Ministry of Health, Labor and Welfare (hereinafter, "MHLW"). This designation will enable us to be at the forefront of innovation, allowing us to use a more extensive consultation system and receive priority review in the processes leading up to early regulatory approval of the Product as a medical device on a global scale.



We are pleased to announce that on February 6, 2025, the Program Medical Device Investigation Committee of the Ministry of Health, Labour and Welfare's Pharmaceutical Affairs and Food Sanitation Council reached a consensus on designating ExaMD's product for priority review.

The MHLW introduced the priority review product designation for SaMD in FY2023. The Ministry comprehensively evaluates products for areas of high medical need, identifying factors such as clinical utility, innovation when compared to existing diagnostic and therapeutic methods, and being developed in Japan ahead of the rest of the world. Since 2023, only a very limited number of products have received this designation.

This ExaMD's product can be used with smartphones, which many people currently own, and can provide diagnostic assistance in about a minute by conducting two short free conversations lasting 30 seconds.

ExaMD is currently working to obtain a business license to manufacture and sell medical devices/apps. We are collaborating with physicians and medical institutions specializing in dementia such as SHOWA University to conduct medical verification, we are aiming to develop a new mobile diagnostic medical apps that is fast, accurate, and easy to use.

☑Development Status and Application for Priority Review

The Product is currently under clinical development and face-to-face advisory consultation with the Pharmaceuticals and Medical Devices Agency (PMDA). We are aiming for faster approval by taking advantage of the following benefits of this priority review product designation:

(1) Priority consultation
(2) Enhanced pre-evaluation (substantially accelerated review)
(3) Priority review
(4) Review partner system (PMDA's version of concierge)

According to an announcement*1 in May 2024, by a research group from MHLW, there will be 5.23 million dementia patients in 2030, an increase of about 800,000 people from 2010, and if mild cognitive impairment (MCI) is included, the number will reach 10 million in the future. They estimate that there will be 152.8 million dementia patients worldwide in 2050, nearly three times the number in 2019*2.

Early detection of dementia is a major social issue, although it is becoming possible to diagnose and treat dementia more effectively at earlier stages.

We believe that the Product can contribute to solving this issue, and we will accelerate its practical application by making the most of this designation.

*1 Conference of Parties Related to the Promotion of Dementia Policies (held on May 8, 2024)
https://www.cas.go.jp/jp/seisaku/ninchisho_kankeisha/dai2/siryou9.pdf
*2 The Lancet Public Health
https://www.thelancet.com/action/showPdf?pii=S2468-2667%2821%2900249-8

☑About ExaMD Inc.

ExaMD was established in February 2024 as an AI service provider specializing in the health and medical fields. The company develops and sells AI-based medical devices and healthcare services, including an AI medical device that diagnoses dementia using conversational voice.

ExaMD Company Profile

Company name: ExaMD Inc.
Location: 4-2-8 Shibaura, Minato-ku, Tokyo, 5F
Established: February 2024
Representative: Koji Hazama, Representative Director
Business: Planning, development, sales, and alliance of products and services using multi-modal AI technology to solve social issues related to healthcare
URL: https://examd.com/

ExaWizards Company Profile

Company name: ExaWizards Inc.
Location: 4-2-8 Shibaura, Minato-ku, Tokyo, 5F

Established: February 2016
Representative: Makoto Haruta, Representative Director & President
Business: Industrial innovation and resolution of social issues via AI service development
URL: https://exawizards.com/en/

<Media Contact>
Exa Wizards Inc. Public Relations: publicrelations@exwzd.com