Revolutionizing Breast Cancer Screening with AI!
AI Breast Cancer Screening "Smaopi" Launched

Supporting physician diagnoses with AI to achieve more reliable breast ultrasound examinations

IRVINE, California – August 19, 2025 – Fixstars Corporation (TSE Prime: 3687, US Headquarters: Irvine, CA), today announced that its subsidiary, Smart Opinion Inc., has completed preparations for the implementation of 'Smart Opinion METIS Eye' (approved as a medical device), an AI (artificial intelligence) tool to assist doctors in diagnosing breast ultrasound (echo) examinations, have been completed and that it will begin operation on August 19, 2025, at the the Keio University Center for Preventive Medicine in Azabudai Hills, Minato-ku, Tokyo. Deployment to additional medical institutions is planned in sequence. Smart Opinion is a joint venture established by Fixstars to socially implement the results of its joint research with Keio University.

With AI, Breast Ultrasound Examinations Become More Reliable

By linking with existing examination equipment, ultrasound image AI diagnostic support software called "Smart Opinion METIS Eye" (hereinafter referred to as METIS Eye) provides

diagnostic support and is capable of detecting even subtle signs of breast cancer that humans might easily miss. It was developed to support a doctor's interpretation while maintaining the conventional easy and painless ultrasound examination, supporting diagnosis with more stable accuracy than ever before, and strengthening the reliability of diagnosis by not overlooking small cancers.

A new concept for AI Breast Cancer Screening: "Smaopi"

We have named screenings utilizing the medical device program METIS Eye as "AI Breast Cancer Screening 'Smaopi'."

Medical institutions that adopt METIS Eye will not replace the physician's diagnosis, but rather use AI as "another pair of eyes" during the physician's diagnosis. By combining "physician's diagnosis + METIS Eye," we will support diagnoses with even more stable accuracy than before.

By utilizing AI, we aim to enhance diagnostic reliability and provide a "more reassuring examination experience" for individuals undergoing breast cancer screening. To achieve this recognition, we will promote the concept of "AI Breast Cancer Screening 'Smaopi'."

Current Status of Breast Cancer Screening and the Issues Smaopi Solves

In Japan, the number of breast cancer patients has been increasing rapidly in recent years. It is currently said that one in nine women will be diagnosed with the disease. A characteristic of breast cancer is a sharp increase in incidence among women in their 40s. This is one of the major social issues that requires an urgent response in a country aiming to create a society where women can play an active role.

Because breast cancer has a high probability of complete recovery and a high survival rate if detected early, breast cancer screening is considered crucial for early detection. However, Japan's breast cancer screening rate is 47%, which is low compared to 70-80% in Western countries, and the mortality rate from breast cancer is increasing year by year.
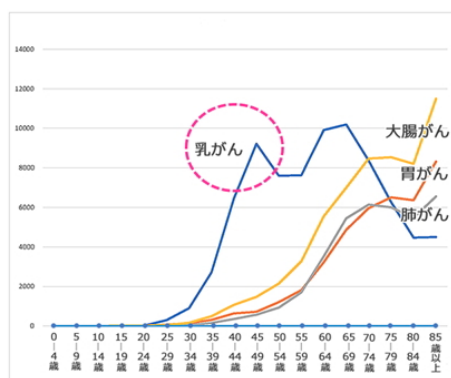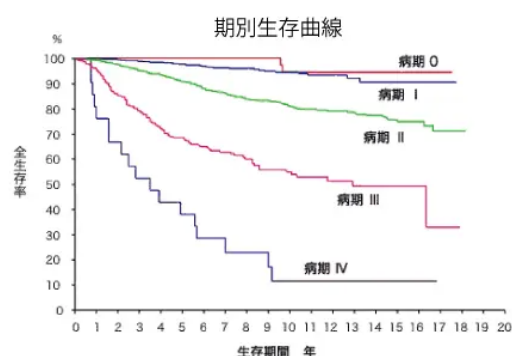
[Number of Breast Cancer Patients (left), Survival Rate by Breast Cancer Stage (right)]

Although palpation and mammography are recommended for breast cancer screening, ultrasound examination is said to be superior to mammography for detecting invasive cancer.

In particular, ultrasound can be performed without a loss of sensitivity even in cases of dense breasts (high-density breast tissue). Dense breasts are extremely common in younger women, and for this reason, about 40% of municipalities have voluntarily introduced ultrasound examinations as one of their breast cancer screening options.

Unlike mammography, an ultrasound examination also has the advantage of being "painless". According to some statistics, about 40% of women who undergo breast cancer screening opt for an echo examination, making ultrasound a primary method of breast cancer screening. On the other hand, a challenge with ultrasound examination has been the variability in accuracy that can arise due to the skill of the examiner.

Smaopi allows for "double reading" by both AI and a person, similar to radiation examinations, in an ultrasound examination, which has many advantages. This leads to stable and accurate diagnoses.

References:

Ministry of Health, Labour and Welfare, "Japan's Low Screening Rate":

https://www.gankenshin50.mhlw.go.jp/campaign_2022/outline/low.html

Survey on the National Lifestyle:

https://ganjoho.jp/reg_stat/statistics/stat/screening/screening.html

First Opinion on Breast Cancer "Dense Breast": https://firstopi.jp/glossary/dense_breast/

About Smart Opinion METIS Eye

- Generic Name: Program for ultrasound workstation
- Trade Name: Breast Cancer Ultrasound Image AI Diagnosis Support Software Smart Opinion METIS Eye
- Approval Number: 30600BZX00086000
- Classification: Controlled Medical Device (Class II)

METIS Eye was developed based on technology resulting from joint research between Keio University and Fixstars Corporation, with the aim of assisting physicians in image interpretation and preventing oversight. It obtained pharmaceutical approval as a medical device program in May 2024. As breast cancer screening is a place to determine whether or not a case requires a detailed examination, it detects candidate lesion sites suspected of requiring a detailed examination and determines the necessity of a detailed examination based on the international standard BI-RADS category classification for those candidate lesion sites.

The detection sensitivity for findings suspected of requiring a detailed examination is 94.4%, and a statistically significant difference was observed between a doctor's diagnosis with and without the AI. When used in conjunction with a Picture Archiving and Communication System (PACS), METIS Eye seamlessly analyzes captured images and saves the results in the PACS.

Doctors can review the analysis results from METIS Eye on the PACS viewer without changing their existing screening workflow, creating a so-called double-reading format.

Reference: BI-RADS Category Classification
https://firstopi.jp/screening/risky_result/risky_result_drhayashida/

[1] Average value of evaluation test results for image interpretation of 50 breast ultrasound images targeting 24 physicians.

"Smart Opinion METIS Eye" Detection Result Image
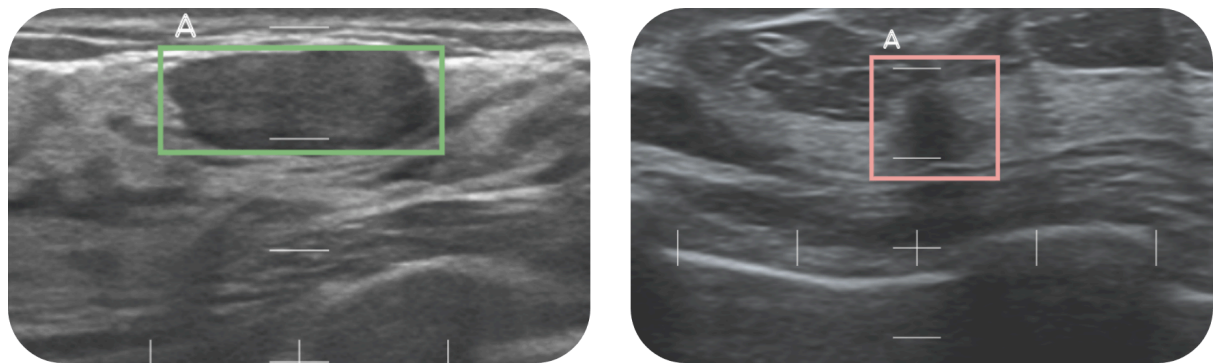
[If the necessity of a detailed examination is suspected, it is indicated by a red box; if not, by a green box.]

Comment from Dr. Satoru Hayashida, Professor, Department of Surgery (Breast Surgery), Keio University School of Medicine, and a joint developer
Breast ultrasound examination can be performed painlessly and is considered highly likely to be a particularly useful examination method for Japanese women, who often have dense breasts. However, there are disparities in diagnostic technology between regions and facilities, which can lead to disadvantages such as oversights and unnecessary detailed examinations. With AI providing diagnostic accuracy at the highest level, I hope this technology will eliminate such disparities and allow women to undergo breast cancer screening with greater confidence.

###

About Smart Opinion
Smart Opinion Inc., established in October 2019 as a joint venture between Fixstars Corporation (Tokyo Stock Exchange Prime: 3687) and Prodigy Medical Inc., contributes to improving early detection of breast cancer and promoting women's health by developing and disseminating "AI Breast Cancer Screening 'Smaopi'", an ultrasound examination that can image-diagnose suspected breast cancer using AI technology. It also provides patient support

services and women's health management support services that realize "patient-centered" healthcare utilizing digital and IT.
https://www.smaopi.com/

About Fixstars Corporation

Fixstars is a technology company dedicated to accelerating AI inference and training through advanced software optimization solutions. It supports innovation in healthcare, manufacturing, finance, mobility, and other industries. For more information, visit: https://www.fixstars.com/

Inquiries regarding implementation

Smart Opinion Inc., Sales Department

Email: contact@smaopi.com

Tel: +81-3-6420-0762

Media Contact

Public Relations, Fixstars Corporation

Email: press@fixstars.com

Tel: +81-3-6420-0751

Smart Opinion Inc., Public Relations

Email: pr@smaopi.com

Tel: +81-3-6420-0762