Sep 9, 2026

Xcoo Files for Manufacturing and Marketing Approval of a SaMD Supporting Expert Panels in Cancer Genomic Medicine

Xcoo, Inc. (Head Office: Bunkyo-ku, Tokyo; CEO: Kunihiro Nishimura; hereinafter "the Company") announces that on September 8th, 2026, it filed an application for manufacturing and marketing approval, under the PMD Act as a Software as a Medical Device (SaMD).

The program the Company is developing to support expert panels in cancer genomic medicine (hereinafter "the Program") was designated by the Ministry of Health, Labour and Welfare (MHLW) on March 29, 2023, as a "Priority Review Product for Program Medical Devices." Building on the research, development, and evaluation conducted to date, the Company has now filed this application.

The Program is currently under application for manufacturing and marketing approval and in Japan.

About Cancer Genomic Medicine and Expert Panels
Cancer genomic medicine involves analyzing the genetic information obtained from a patient's cancer tissue, blood, or other samples, and concluding diagnosis and treatment approaches by comparing the sample information against medical and scientific knowledge. The cancer genomic profiling (CGP) testing began to be covered by Japan's public health insurance system in June 2019. As of July 31, 2026, cumulative registrations with the National Cancer Center's (NCC) Center for Cancer Genomics and Advanced Therapeutics (C-CAT) has totaled 141,241 patients since insurance coverage.

In CGP testing, an expert panel (molecular tumor board), a multidisciplinary conference of specialists in cancer drug therapy, medical genetics, pathology, genomic medicine, and related fields, is convened to conduct a medical review of the test results. Due to the nature of information related to cancer, including genetic data, therapeutic agents, clinical trials, clinical practice guidelines, and medical literature, is continuously updated, expert panels must collect and organize this information before reviewing test results.

Through collaboration with multiple medical and research institutions, the Company has worked to identify challenges in the clinical practice of cancer genomic medicine and to develop and evaluate systems addressing them. In this process, the Company has pursued research and development of technology to support expert panels through the analysis and interpretation of information in cancer genomic medicine, which has advanced the Program as a SaMD intended for use in clinical settings. The Program was designated by the MHLW on March 29, 2023, as a "Priority Review Product for Program Medical Devices," and the Company has now filed for manufacturing and marketing approval. Going forward, the Company will respond to the regulatory review process toward obtaining approval for the Program.

About Xcoo, Inc.
Since its founding in 2011, Xcoo, Inc. has focused on research and development in the analysis and interpretation of medical information and related software technologies, centered on cancer genomic medicine and the field of Precision Oncology. Under the goal of "delivering genomic medicine correctly to patients," the Company develops and provides a total genomic and multi-omics solution. In addition to providing services to medical institutions engaged in cancer genomic medicine in Japan, the Company is also engaged in research, development, and business expansion overseas. In March 2025, the Company signed a Memorandum of Understanding with Thailand's Ministry of Public Health Medical Life Sciences Institute, the Siriraj Genomics Center (Faculty of Medicine Siriraj Hospital, Mahidol University), and N Health Novogene Genomics for the joint development of an AI-powered platform for interpreting cancer gene variants.

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- Founded: April 2011
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Notes Regarding This Program
The Program is an unapproved medical device that is currently pending approval for manufacturing and marketing in Japan. It has not yet obtained manufacturing and marketing approval. This press release is intended to provide information regarding the Company's corporate activities in research and development and its status in application for manufacturing and marketing approval. Filing this application does not guarantee that approval will ultimately be obtained.

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