

May 7, 2024



Independent Study Results in Japan Demonstrate Zero (0%) Breast Cancer Local Recurrence 5 Years Following Treatment with IceCure's ProSense®, Adding to Continued Positive Data Published Globally

- *Study published in the peer reviewed journal Breast Cancer*
- *Excellent cosmetic outcomes, high degree of patient satisfaction, and improved quality of life post-cryoablation*
- *Strategic distribution partner of ProSense® in Japan, Terumo Corporation, expects to submit an application for regulatory clearance for breast cancer in the second half of 202*

CAESAREA, Israel, May 7, 2024 /PRNewswire/ -- [IceCure Medical Ltd.](#) (Nasdaq: ICCM) ("IceCure" or the "Company"), developer of the ProSense® System, a minimally-invasive cryoablation technology that destroys tumors by freezing as an alternative to surgical tumor removal, announced today that positive data from an independent study (the "Study") performed in Japan was published in an article titled "Percutaneous ultrasound-guided cryoablation for early-stage primary breast cancer: a follow-up study in Japan," in the journal *Breast Cancer* on April 27, 2024. The Study, which focused on the local control of cancer, safety, patient quality of life, patient satisfaction, and cosmetic outcomes of cryoablation for patients with early-stage breast cancer, is the continuation of a [prior pilot study](#) that demonstrated percutaneous cryoablation treated with ProSense® is a potential standard treatment for early-stage breast cancer patients, given compliance to pre-defined patient selection criteria.



The Study was led by Dr. Hisanori Kawamoto, M.D., Ph.D. from the Department of Breast Surgery, Breast and Imaging Center at St. Marianna University School of Medicine in Japan. Eighteen early-stage breast cancer patients, with a mean age of 59.0 [± 9.0 years], with a mean tumor size of 9.8 ± 2.3 mm, who underwent treatment with ProSense® were followed for a mean of 44.3 months. No patients had local recurrence or distant metastasis in the 5-year follow-up. No serious adverse events were reported. Cosmetic outcomes were excellent and the overall patient satisfaction level and patient quality of life improved post-cryoablation.

The article states that minimally invasive non-surgical techniques, including cryoablation, aim for curative outcomes while also acknowledging the importance of preserving or enhancing the quality of life and cosmetic appearance following the procedure. The authors of the Study refer to recent trials, including IceCure's ICE3 trial, for evidence that cryoablation results in local cancer control rates comparable to lumpectomies in early-stage breast cancer patients.

Dr. Kawamoto commented, "This is a very important study in Japan, where we are experiencing an upward trend in breast cancer cases, especially among women in their late 40s to early 60s. These are women who often are at very active stages of their life and therefore there is a growing demand for treatment options that minimize the chance of or avoid hospitalization, in addition to resulting in favorable clinical and cosmetic outcomes. We are very pleased with these results and are hopeful that ProSense® may become a favored option in Japan upon regulatory approval for early-stage breast cancer."

"We thank Dr. Kawamoto and his colleagues for conducting this independent study, which adds to the growing body of efficacy and safety data for ProSense® as a minimally-invasive option for early-stage breast cancer," stated IceCure CEO, Eyal Shamir. "We anticipate that our in-country distribution partner, Terumo Corporation, will file for regulatory clearance of ProSense® for breast cancer in Japan later this year, which may soon lead to the approval and commercialization for it in a market where there is high demand for a minimally-invasive option."

Terumo Corporation owns the exclusive distribution rights for ProSense® in Japan for a 5-year term following regulatory approval. In exchange for exclusive distribution rights, IceCure is expected to receive a total of \$13.2 million in proceeds from Terumo during this initial term, of which it has received \$4 million to date, with an additional \$8.2 million expected upon the completion of orders, as well as \$1 million expected for milestone-based payments.

About ProSense®

The ProSense® Cryoablation System provides a minimally invasive treatment option to destroy tumors by freezing them. The system uniquely harnesses the power of liquid nitrogen to create large lethal zones for maximum efficacy in tumor destruction in benign and cancerous lesions, including breast, kidney, lung, and liver.

ProSense® enhances patient and provider value by accelerating recovery, reducing pain, surgical risks, and complications. With its easy, transportable design and liquid nitrogen utilization, ProSense® opens that door to fast and convenient office-based procedure for breast tumors.

About IceCure Medical

IceCure Medical (Nasdaq: ICCM) develops and markets ProSense®, an advanced liquid-nitrogen-based cryoablation therapy for the treatment of tumors (benign and cancerous) by freezing, with the primary focus areas being breast, kidney, bone and lung cancer. Its minimally invasive technology is a safe and effective alternative to hospital surgical tumor removal that is easily performed in a relatively short procedure. The system is marketed and sold worldwide for the indications cleared and approved to date including in the U.S., Europe, and China.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements. For example, IceCure is using forward looking statements in this press release when it discusses: that percutaneous cryoablation treated with ProSense® is a potential standard treatment for early-stage breast cancer patients, the growing demand for minimally invasive treatment options, the hope that ProSense® may become a favored option in Japan upon regulatory approval for early-stage breast cancer, the expectation that Terumo Corporation will file for regulatory clearance in the second half of 2024, and the expected proceeds of IceCure in connection with its exclusive distribution rights agreement with Terumo. Historical results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials will suggest identical or even similar conclusions. Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among others: the Company's planned level of revenues and capital expenditures; the Company's available cash and its ability to obtain additional funding; the Company's ability to market and sell its products; legal and regulatory developments in the United States and other countries; the Company's ability to maintain its relationships with suppliers, distributors and other partners; the Company's ability to maintain or protect the validity of its patents and other intellectual property; the Company's ability to expose and educate medical professionals about its products; political, economic and military instability in the Middle East, specifically in Israel; as well as those factors set forth in the Risk Factors section of the Company's Annual Report on Form 20-F for the year ended December 31, 2023 filed with the U.S. Securities and Exchange Commission (the "SEC") on April 3, 2024, and other documents filed with or furnished to the SEC which are available on the SEC's website, www.sec.gov. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.

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