October 19, 2022

IceCure Files De Novo Classification Request with the FDA for Marketing Authorization of ProSense® with Breakthrough Indication: Early-Stage Low-Risk Breast Cancer Patients at High Risk to Surgery

- ***43,000 cases estimated annually in the U.S. alone for indication in initial filing representing an estimated $80 million annual addressable market***
- ***65,000 cases estimated annually in the U.S. for broader indication Company intends to file based on FDA's guidance, reflecting the full ICE3 study population after ICE3 5-year follow-ups are completed for all patients in 2024***
- ***To date, the Ipsilateral Breast Tumor Recurrence (IBTR) rate for the entire study population is 3.09%***
- ***Submission data include IBTR as the primary endpoint***

CAESAREA, Israel, Oct. 19, 2022 /PRNewswire/ -- IceCure Medical Ltd. (Nasdaq: ICCM) (TASE: ICCM) ("IceCure" or the "Company"), developer of minimally-invasive cryoablation technology, the ProSense® System that destroys tumors by freezing, today announced it submitted a regulatory filing (De Novo Classification Request) with the U.S. Food and Drug Administration ("FDA") for marketing authorization based on ICE3 clinical trial ("ICE3") interim analysis of ProSense for the indication of early-stage (Luminal A T1 invasive) low-risk breast cancer in patients who are at high risk to surgery (not suitable for surgical alternatives), representing approximately 43,000 women in the U.S. annually. The specific indication filed is based on interim data and is in accordance with discussions IceCure has had with the FDA, which granted ProSense Breakthrough Device Designation, enabling closer communications regarding its regulatory filing.

ICE3 is the largest controlled, multicenter clinical trial ever performed in the U.S. for liquid nitrogen-based cryoablation of small, low-risk, early-stage malignant breast tumors. To date, there have been six cases of ipsilateral breast tumor recurrence ("IBTR") out of 194 patients, or 3.09%. The survival-based estimate for the 5-year IBTR is 4.3% with a one-sided 95% confidence level, upper bound of 8.4% for the entire study population. Final ICE3 5-year follow-up data are expected in the first half of 2024, at which time IceCure plans to file with the FDA for a broader indication reflecting the entire study population—early-stage (Luminal A T1 invasive) low-risk breast cancer for patients age 60 and over, representing approximately 65,000 women in the U.S. annually.

The total group of Luminal A breast cancer for women in all ages, is estimated at 144,000

cases annually in the U.S. In the future, IceCure intends to explore more indications for additional sub groups that are part of the total group of Luminal A breast cancer.

Approximately 66% of the ICE3 patients were determined to be at high risk to surgery due to factors including age and co-morbidities. For these patients, their doctors, and insurers, cryoablation may offer significant benefits as compared to lumpectomy, the current standard of care, including less risk of complications, lower cost, superior cosmetic results, rapid recovery, higher physician and patient satisfaction, and the convenience of a fast and simple in-office procedure.

Data suggests the use of ProSense cryoablation in breast procedures eliminates the risk of re-excision (a second surgery). Between 14% - 20% of breast cancer surgeries result in re-excision due to the practice of requiring a margin of normal breast tissue beyond the involved malignant tissue. This is associated with greater morbidity, patient anxiety, poorer cosmetic outcomes, and increased cost.

"We are very pleased to be in a position to file for regulatory approval with the FDA in this specific breast cancer indication prior to our full study read out expected in 2024 and backed by what we believe is the most extensive data available in the field of breast cancer cryoablation. Following our pre-submission package to the FDA last year, we have been in discussions with the regulatory body regarding this two-step approach for the specific indications for which we are applying. While we await the full study read out of the ICE3 trial, we believe that our first submission makes a strong case for approval based on our interim analyses of the ICE3 data, highly favorable patient outcomes, and improved healthcare economics," stated IceCure CEO Eyal Shamir. "We hope to give women a new option that is just as effective as lumpectomy, without the risk of surgery in the U.S. and globally. If the FDA grants the De Novo Request for ProSense in breast cancer, this may support our global commercialization efforts, as doctors, distributors, and regulatory agencies around the world tend to consider a device's FDA status in their decision-making."

IceCure is committed to making ProSense widely available and affordable upon regulatory approval by elucidating the procedure's healthcare economics and through reimbursement and CPT codes. The Company will continue to follow the development of CMS's new pathway for coverage of innovative new devices, Transitional Coverage of Emerging Technology ("TCET"), which is replacing the repealed Medicare Coverage of Innovative Technologies ("MCIT") rule. CMS is expected to share more about TCET with the public for comments after April 2023.

In addition, IceCure continues to work closely with the ASBrS toward a potential registry trial targeting ASBrS treatment guideline amendments following trial results.

About ICE3

ICE3 is the largest controlled multi-location clinical trial ever performed for liquid nitrogen (LN2) –based cryoablation of small, low-risk, early-stage malignant breast tumors without subsequently removing them. The trial began in 2014 and has completed recruitment of 206 patients (of which 194 were eligible for cryoablation) in 19 hospitals and medical centers across the U.S., including Columbia University Medical Center and Mount Sinai Beth Israel.

About IceCure Medical Ltd.

IceCure Medical Ltd. (NASDAQ: ICCM) (TASE: 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 to-date by the U.S. Food and Drug Administration and approved in Europe with the CE Mark.

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 the estimated size of the addressable market in the United States, its intentions to explore and expand regulatory approvals and distribution of ProSense for various indications, the completion of ICE3 5-year follow-up in 2024, our belief that our first submission makes a strong case for approval based on our interim analyses of the ICE3 data, the significant benefits cryoablation may offer as compared to lumpectomy to patients at high risk to surgery, exploring additional indications of Luminal A breast cancer's related sub groups, the potential for the Company's global commercialization efforts to be supported if the FDA grants the De Novo Request for ProSense in breast cancer and its efforts to establish ProSense as a widely available and affordable alternative to lumpectomy and the potential registry trial targeting ASBrS treatment guideline amendments following trial results.

Because such statements deal with future events and are based on IceCure's current expectations, they are subject to various risks and uncertainties and actual results, performance, or achievements of IceCure could differ materially from those described in or implied by the statements in this press release. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, many of which are beyond the control of the Company, including those set forth in the Risk Factors section of the Company's Annual Report on Form 20-F for the year ended December 31, 2021 filed with the Securities Exchange Commission (the "SEC") on April 1, 2022, as amended, which is 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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