August 7, 2024

IceCure Announces Positive Data from the Largest Multi-Institutional Study of its Kind: "Cryoablation of Primary Breast Cancer in Patients Ineligible for Clinical Trials"

- ***Investigator initiated independent study included higher risk patients such as those with metastatic disease, large tumors, and comorbidities, as compared to IceCure's ICE3 study which treated early-stage breast cancer patients***
- ***Recurrence-free rates were 94.7%, 87.8%, and 81.8%, at 1, 2, and 3 years, respectively***
- ***Study published in American Journal of Roentgenology was conducted at 7 U.S. institutions and led by Principal Investigators Dr. Karim Oueidat and Dr. Robert Ward, both of the Warren Alpert Medical School of Brown University***

CAESAREA, Israel, Aug. 7, 2024 /PRNewswire/ -- IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure", "IceCure Medical" or the "Company"), developer of minimally-invasive cryoablation technology that destroys tumors by freezing as an alternative to surgical tumor removal, today announced the publication of an independent study titled "Cryoablation of Primary Breast Cancer in Patients Ineligible for Clinical Trials: A Multi-institutional Study" in a leading radiology journal, the *American Journal of Roentgenology* (AJR).

This multi-institutional study is the largest study of breast cancer cryoablation in women ineligible for prospective clinical trials due to particular patient or tumor characteristics. IceCure's ICE3 study, which evaluated the Company's ProSense® cryoablation system, enrolled early-stage breast cancer patients only. Based on the ICE3 results, IceCure has filed for regulatory approval of ProSense® in the U.S. for the indication of treating patients with early stage T1 invasive breast cancer with cryoablation and adjuvant hormone therapy.

As reported in the AJR, the independent study evaluated 112 patients with a median age of 71. ProSense® was one of four different cryoablation systems used for procedures performed at 7 U.S. institutions by 7 different radiologists, including 4 breast radiologists, 2 breast and interventional radiologists, and 1 interventional radiologist. The recurrence-free rates were 94.7%, 87.8%, and 81.8%, at 1, 2, and 3 years, respectively, when accounting for death, including from comorbidities, as a competing risk. Treatment with cryoablation had a low frequency of adverse events (AEs), with 6.3% of patients having minor AEs and no moderate or major AEs having occurred. A high frequency of procedures, 98.2%, were technically successful. The researchers concluded that in certain individuals with unfavorable patient or tumor characteristics, cryoablation remains a safe alternative to surgery that has overall good outcomes, especially in patients who are poor surgical candidates due to comorbidities. Patients in the independent study generally underwent cryoablation based on their preference for cryoablation.

"This study underscores the opportunity for cryoablation with ProSense® to offer a much-needed non-surgical alternative for women who may not be eligible for surgery," stated IceCure CEO Eyal Shamir. "It is important to note that the researchers found cryoablation to be a safe procedure with good outcomes, even in this higher risk population, which included patients with metastatic disease, large tumors, and more than half of the study participants having comorbidities. We thank the researchers and institutions for their initiative and participation in this independent study."

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 advanced liquid-nitrogen-based cryoablation therapy systems 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 Company's flagship ProSense® 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 the conclusion from the study that cryoablation remains a safe alternative to surgery that has overall good outcomes, especially in patients who are poor surgical candidates due to comorbidities, and that the study underscores the opportunity for cryoablation with ProSense® to offer a much-needed non-surgical alternative for women who may not be eligible for surgery. 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 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.

IR Contact:

Email: investors@icecure-medical.com
Michael Polyviou
Phone: 732-232-6914
Todd Kehrli
Phone: 310-625-4462

Logo - https://mma.prnewswire.com/media/2319310/IceCure_Medical_Logo.jpg

View original content:https://www.prnewswire.com/news-releases/icecure-announces-positive-data-from-the-largest-multi-institutional-study-of-its-kind-cryoablation-of-primary-breast-cancer-in-patients-ineligible-for-clinical-trials-302216520.html

SOURCE IceCure Medical