May 4, 2021

Positive Interim Results from IceCure Medical's ICE3 Clinical Trial for Breast Cancer Treatment by Freezing with the ProSense® Cryoablation System Presented at the 2021 ASBrS Meeting

CAESAREA, Israel, May 4, 2021 /PRNewswire/ -- IceCure Medical Ltd. (TASE: ICCM) ("IceCure" or the "Company"), developer of the minimally invasive cryoablation ProSense® System that destroys tumors by freezing, today announced interim results from the Company's ICE3 clinical trial for cryoablation of small low-risk breast cancer tumors. At a mean of 34.83 months following treatment with ProSense®, only 2.06% (4 out of 194 eligible trial patients) experienced cancer recurrence.

Interim results were presented at the 22nd Annual Meeting of the American Society of Breast Surgeons (ASBrS) by Dr. Richard Fine, MD, FACS, an ICE3 investigator who serves as Program Director of the Breast Surgical Oncology Fellowship and as Director of Research and Education at the West Comprehensive Breast Center in Germantown, TN, who previously served as Chairman of the ASBrS. In a press release issued by the ASBrS, Dr. Fine stated that "cryoablation potentially represents a dramatic improvement in care for appropriate low-risk patients, and at three years post-treatment, the ICE3 trial results are extremely positive. The non-invasive procedure is fast, painless and can be delivered under local anesthesia in a doctor's office. Recovery time is minimal and cosmetic outcomes are excellent with little loss of breast tissue and no scarring. Now, this trial is underscoring the efficacy and safety of the procedure for this patient group."

The ICE3 trial commenced in 2014 and is, to the best of the Company's knowledge, the largest controlled multisite clinical trial conducted in the U.S. for liquid nitrogen-based cryoablation of early-stage malignant breast tumors. The study was conducted in 19 hospitals and medical centers across the U.S., including Columbia University Medical Center and Mount Sinai Beth Israel. The ICE3 trial enrolled and treated 194 patients 55 years of age or older (average age of 75) with low-risk, early-stage breast cancer tumors measuring up to 1.5 cm. Patients were treated with IceCure's ProSense® Cryoablation System, a minimally-invasive approach to directly target and freeze tumors. Duration of treatment ranged from 20 to 40 minutes depending on the location and size of the tumor. Treatment does not require surgical incision or involve scarring.

At a mean of 34.83 months following treatment with ProSense®, only 2.06% (4 patients) experienced cancer recurrence. The 36-month local Failure Free Probability is 99.22%. The statistical analysis presented by Dr. Fine indicates that among patients treated using the company's ProSense® Cryoablation System, the chance of non-recurrence in a population

of patients with low-risk breast cancer, in early stages, and up to 1.5 cm tumor size, for a period of up to three years, is between 94.58%% and 99.89%%, with a statistical significance (confidence level) of 95%. He also reported that freezing low risk breast tumors in the early stages delivers greater patient satisfaction at a lower cost than traditional interventions. "Less aggressive therapies can be as effective and deliver greater patient satisfaction at a lower cost than traditional interventions," said Dr. Fine. "In keeping with that trend, cryoablation is a promising, high value treatment for certain forms of less aggressive cancers." No significant device-related adverse events were reported. 95% percent of patients and 98% of treating physicians reported satisfaction with the cosmetic results.

Dr. Fine cited the December 2017 ASBrS Consensus Guideline on Breast Cancer Lumpectomy Margins that states"[i]n a recent meta-analysis, the effect of margin status and margin distance on IBTR in patients with early-stage invasive breast cancer was evaluated in 21 studies that identified 1,026 local recurrences in 14,571 patients," indicating that local recurrences resulted in surgery for 7.04% of patients evaluated.

"We are extremely encouraged by the strong interim results from our ICE3 trial," commented Eyal Shamir, Chief Executive Officer of IceCure. "These results further validate ProSense® as a safe and effective minimally-invasive cryoablation approach to tumor destruction, and we look forward to continuing our productive dialogue with the ASBrS and the FDA on advancing the process of making this valuable technology available for patients with malignant breast tumors. We are hopeful that this data, combined with the FDA's Breakthrough Device Designation, will help expedite commercialization of ProSense® for breast cancer treatment in the U.S."

IceCure expects that by June 2021 there will be 49 patients that have completed a five-year follow-up, 41 patients that have completed a four-year follow-up, 39 patients that have completed a three-year follow-up, and 51 patients that have completed a two-year follow-up.

About IceCure Medical

Founded in 2006, Israel-based IceCure Medical (TASE: ICCM), develops and markets 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, after receiving FDA and CE approvals. To learn more, please visit: www.icecure-medical.com.

Forward Looking Statements

The Company's foregoing assessments in relation to the assistance of the experiment's results in obtaining FDA approval to treatment of Breast cancer tumors, to strengthen the ASBrS recognition and to the commercialization of the Company's products, are considered Forward-Looking statements, as defined in the Israeli Securities Law, 5728-1968, which depends on factors outside the Company's control, including without limitations, the Company's compliance with the FDA requirements and the actual adoption of the Company's products by the medical community. In light of the foregoing, these assessments might not materialize or materialize significantly differently than described above.

Communication Contact:
Tlalit Bussi Tel Tzure
VP BD & Marketing
IceCure Medical Ltd
+972-545-650-737
tlalitb@icecure-medical.com

IR Contact:
Jeremy Feffer
T: 212-915-2568 | M: 917-749-1494
jeremy@lifesciadvisors.com

View original content:http://www.prnewswire.com/news-releases/positive-interim-results-from-icecure-medicals-ice3-clinical-trial-for-breast-cancer-treatment-by-freezing-with-the-prosense-cryoablation-system-presented-at-the-2021-asbrs-meeting-301282841.html

SOURCE IceCure Medical