April 30, 2025

IceCure Announces Positive FDA Development: Understanding on Path Forward for Marketing Authorization of ProSense® Cryoablation in Women 70+ with Early-Stage Breast Cancer

- ***Final marketing authorization decision for early-stage breast cancer is expected upon the FDA's approval of IceCure's post-market study plan***
- ***IceCure to engage with potential clinical sites, breast surgeons and radiologists for the post-market study including at the upcoming American Society of Breast Surgeons (ASBrS) Annual Meeting***
- ***ProSense® would become the first-in-class minimally invasive choice—a major advancement in women's health and a new paradigm in breast cancer care as a simple out-patient procedure***
- ***U.S. sales and distribution team ready to drive sales of ProSense® systems and disposable probes—supporting medical community and patients looking for a new minimally invasive option to lumpectomy***

CAESAREA, Israel, April 30, 2025 /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 it concluded a productive meeting with the leadership of the U.S. Food and Drug Administration's ("FDA") Center for Devices and Radiological Health ("CDRH") regarding the Company's De Novo marketing authorization request for ProSense® in the treatment of early-stage low risk breast cancer when combined with adjuvant endocrine therapy for women aged 70 and over which represents approximately 46,000 patients annually in the U.S.

During the meeting, the FDA requested that IceCure conduct a study after marketing authorization has been granted ("the post-market study"), with the aim of producing additional data in this indication. IceCure will present its post-market study plan, which is expected to include a minimum of 400 patients at 25 sites, to the FDA, and upon the CDRH's approval of such plan, the FDA's final marketing authorization decision is expected.

IceCure is now working diligently on the plan of the post-market study which IceCure plans to submit in approximately a few weeks. The Company is in the process of recruiting clinical sites and doctors across the U.S., including at the American Society of Breast Surgeons (ASBrS) Annual Meeting which takes place April 30 – May 4, 2025. The Company believes this post-market study will support accelerated market adoption of ProSense® in early-stage breast cancer.

"This is a very positive development, and we are pleased to have had such a positive discussion with the FDA's CDRH leadership so that women aged 70 and over across America can have access to a minimally invasive option for early-stage breast cancer with ProSense®," stated Eyal Shamir, IceCure's Chief Executive Officer. "We are laser focused on the plan of our post-market study and look forward to finalizing it following deep engagement with the leading breast surgeons and radiologists in the U.S., including at ASBrS this week. As such, the meeting with the FDA is very well timed. We look forward to the FDA's approval of our post-market study plan and final marketing authorization decision for ProSense® in this indication. Our U.S. sales team is ready for commercialization."

Post-market study procedures will have access to reimbursement under the CPT III code, which covers $3,800 of facility costs. IceCure expects additional reimbursement coverage in the future pending the FDA's marketing authorization and other factors, including the post-market activity and recommendations from professional medical associations, including the ASBrS.

About ProSense®

The ProSense® Cryoablation System is a minimally invasive cryosurgical tool that provides the 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 procedures for breast tumors.

About IceCure Medical

IceCure Medical (Nasdaq: ICCM) develops and markets advanced liquid-nitrogen-based cryoablation therapy systems for the destruction 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 Asia.

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 prospective post-market study plan, the Company's intention to submit such plan in approximately a few weeks and the presentation of the post-market study plan; the expectation of the FDA's final marketing authorization decision for ProSense® upon the CDRH's approval of the post-market study plan; the Company's belief that the post-market study will support accelerated market adoption of ProSense® in early-stage breast cancer; the Company's prospective engagement with leading breast surgeons and radiologists in the U.S. to finalize the post-market study; and the belief that the Company's U.S. sales team is ready for commercialization. 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, 2024 filed with the SEC on March 27, 2025, 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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