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IceCure Reports Updated Timeline and Progress with FDA Regarding Marketing Authorization for ProSense® Cryoablation in Early-Stage Breast Cancer

IceCure working in close collaboration with FDA towards De Novo decision

CAESAREA, Israel, March 20, 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 is in continued discussions with the U.S. Food and Drug Administration ("FDA") regarding its De Novo marketing authorization request for ProSense® in early-stage low risk breast cancer with endocrine therapy. The Company now expects the FDA's marketing authorization decision to be reached after the first quarter of 2025.

"Given the novelty of our product and the importance of breast cancer in public health, the FDA has included many stakeholders in the discussion of the De Novo marketing clearance for ProSense® for the treatment of early-stage, low-risk breast cancer with endocrine therapy" stated IceCure's Chief Executive Officer, Eyal Shamir.

"We appreciate the attention of many at the FDA despite the evolving situation at the agency as we work productively together towards a decision on marketing authorization," Shamir added.

Due to the public health importance of breast cancer, the FDA convened a Medical Device Advisory Committee Panel ("Advisory Panel") in November 2024 to obtain independent non-binding expert advice on scientific, technical and policy matters related to the potential granting of marketing authorization of ProSense® for treating patients with early-stage low risk breast cancer with endocrine therapy. The Advisory Panel, which included breast surgeons, interventional radiologists, breast oncologists, and representatives from the

patient, consumer, and regulatory communities, voted in favor of ProSense®'s benefit-risk profile in early-stage low risk breast cancer.

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 expected timing of the FDA's marketing authorization decision. 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.

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