November 15, 2023

IceCure Medical Files Appeal with U.S. FDA Requesting a Review of its De Novo Classification for ProSense® in Early-Stage Breast Cancer

- ***Objective is to reopen file to address comments and find appropriate comparator group that is more representative of the patient population the Company is seeking to treat with its ProSense® system***
- ***Company seeks to complete the review process, establish special controls, and finalize classification of ProSense®***

CAESAREA, Israel, Nov. 15, 2023 /PRNewswire/ -- IceCure Medical Ltd. (Nasdaq: ICCM), developer of the ProSense® System, a minimally-invasive cryoablation technology that destroys tumors by freezing as an alternative to surgical tumor removal, today announced it has filed a request for supervisory review ("appeal") under 21 CFR 10.75 with the U.S. Food and Drug Administration ("FDA") regarding the agency's denial of the Company's De Novo Classification Request for treating patients with early-stage, low risk breast cancer.

IceCure filed the De Novo request with the FDA in October 2022 based on interim data from its ICE3 breast cancer study for the Breakthrough Indication of early-stage (Luminal A T1 invasive) low-risk breast cancer patients. The interim ICE3 results, which estimate a five-year 95.7% recurrence free rate, and 100% doctor and patient satisfaction with cosmetic results, were submitted in the De Novo request in an effort to make the breakthrough minimally-invasive cryoablation procedure available to women in the U.S. sooner.

On September 20, 2023, IceCure announced that the FDA denied its De Novo request. The

Company believes the FDA's response is largely due to the agency's choice of comparator group against which the ICE3 interim results were evaluated. During the appeal process, the Company is committed to working with the FDA to identify a comparator group that is more appropriate and representative of the patient population it is seeking to treat with its ProSense® system. Per the FDA's guidelines, IceCure expects a response to its appeal by the end of January 2024.

The ICE3 study is expected to be completed in the first quarter of 2024 following the last patient's five-year follow-up exam. Furthermore, the FDA's decision regarding the De Novo Classification request for breast cancer has no effect on ProSense®'s FDA cleared authorization for other indications in the U.S., and patients continue to have access to and benefit from ProSense® for those indications. Outside of the U.S., ProSense® is approved for early-stage breast cancer in numerous countries, including in the European Union, Brazil, and China.

"We believe the appeal process allows us to work with the FDA to identify an appropriate comparator group and that a subsequent analysis of the data may support the granting of the De Novo submission and marketing authorization," commented Eyal Shamir, Chief Executive Officer. "Furthermore, we believe the wealth of published studies in the scientific literature, including meta-studies, offer proper comparator groups that demonstrate that ProSense® is a minimally invasive alternative solution as compared to the current standard of care lumpectomy, in the Breakthrough Indication of early-stage, low-risk breast cancer patients."

About ProSense®

ProSense® cryoablation is a minimally invasive, non-surgical, outpatient 40-minute procedure that only requires a local 1% lidocaine injection (similar to its use by dentists when performing certain dental procedures) enabling the patient to remain alert during the procedure and then walk out of the doctor's office to resume their day. Cryoablation costs less than the current standard of care breast cancer surgery of lumpectomy or partial mastectomy, which requires general anesthesia and has cosmetic consequences.

About IceCure Medical

IceCure Medical (Nasdaq: 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 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: its objectives in its appeal of the FDA's De Novo Classification request; its plans to work with the FDA to identify a comparator group that is more appropriate and representative of the patient population seeking to be treated with the ProSense® system; the expected response from the FDA to the Company's appeal by the end of January 2024; the expected timing to complete the ICE3 trial in the first quarter of 2024; and that a subsequent analysis of the ICE3 data may lead to granting of the De Novo submission and marketing authorization. Historic 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. 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. 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: our planned level of revenues and capital expenditures; our available cash and our ability to obtain additional funding; our ability to market and sell our products; legal and regulatory developments in the United States and other countries; our ability to maintain our relationships with suppliers, distributors and other partners; our ability to maintain or protect the validity of our patents and other intellectual property; our ability to expose and educate medical professionals about our 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, 2022 filed with the SEC on March 29, 2023, 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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