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U.S. Food and Drug Administration Grants Regulatory Clearance to IceCure for Next-Gen XSense™ Cryoablation System with CryoProbes

CAESAREA, Israel, July 1, 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 it has received marketing authorization from the United States Food and Drug Administration (the "FDA") for its next-generation single probe cryoablation system, the XSense™ Cryoablation System with CryoProbes.



"This latest FDA regulatory clearance further validates the safety and efficacy of our platform cryoablation technology," commented Eyal Shamir, IceCure's Chief Executive Officer. "The next-generation XSense™ system is cleared for the same indications as our flagship ProSense® system and we believe it has future potential to address other indications in the U.S. for significant indications with unmet needs. Through our innovation, IceCure is a global leader in liquid nitrogen-based cryoablation systems that offer a new minimally invasive treatment with benefits for patients, doctors and payors alike."

XSense™ and its cryoprobes are cleared for all of the indications for which ProSense® has already received the requisite FDA clearance, including general minimally invasive cryoablation in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology and urology. The system is designed to destroy tissue by the application of extreme cold temperatures, including fibroadenomas, kidney tissue, liver metastases, tumors, skin lesions and warts.

About IceCure's Cryoablation Systems

IceCure's platform technology, including the ProSense® Cryoablation System and XSense™

Cryoablation System and CryoProbes, provides a minimally invasive treatment option to destroy tumors by freezing them. The systems uniquely harness 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.

IceCure's cryoablation systems enhance patient and provider value by accelerating recovery, reducing pain, surgical risks and complications. With easy, transportable design and liquid nitrogen utilization, ProSense® and XSense™ open the 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 belief that XSense™ has future potential to address other indications in the U.S. for significant indications with unmet needs. 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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