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IceCure Medical Announces Updated Regulatory Strategy in China for the IceSense3® System to Treat Cancerous Tumors with Cryoablation

IceCure submitted an amendment to the registration certificate granted for the IceSense3 System by China's NMPA, which will allow IceCure to sell its IceSense3 and Cryoprobes for commercial procedures in China

CAESAREA, Israel, Oct. 12, 2021 /PRNewswire/ -- IceCure Medical Ltd. (NASDAQ: ICCM) (TASE: ICCM) ("IceCure" or the "Company"), developer of the next generation minimally invasive cryoablation technology that destroys tumors by freezing, today announced the advancement of its regulatory strategy in China with the submission of an amendment to the registration certificate for the IceSense3® system, which was granted by China's National Medical Products Administration ("NMPA"). The amendment, if approved, will allow the Company to sell its disposable IceSense3 Cryoprobes for commercial procedures. The Company expects the NMPA to complete its evaluation of the amendment by the end of 2022. If the amendment is approved, the Company expects to then launch its commercial sales program for the IceSense3 system in China in early 2023.

"We are excited to announce the advancement of our regulatory strategy for the IceSense3 system in China, as we look to bring our minimally-invasive therapy to more cancer patients around the world. With more than 400,000 new breast cancer cases diagnosed in China in 2020, according to the World Health Organization, breast cancer continues to be a significant health concern in China," commented Eyal Shamir, Chief Executive Officer of IceCure. "As Chinese health providers continue to look for advanced technologies, we expect early adopters in China to provide a base for our commercial launch once the IceSense3 Cryoprobes receive NMPA regulatory clearance. As part of our strategy to gain greater awareness of our systems and cryotherapy as a cancer treatment more broadly with healthcare providers in the region, we have been supportive of an ongoing independent clinical trial with a site in Hong Kong and a site in Shenzhen. Also, we expect another independent trial to start soon in a leading hospital in Shanghai."

About IceCure Medical

Founded in 2006, Israel-based IceCure Medical (NASDAQ: ICCM) (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 in an outpatient facility. The system is marketed and sold worldwide, after receiving certain FDA and CE approvals.

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 statement in this press release when it discusses the development of distribution networks for its products, the Company's regulatory strategy and developing a regulatory path towards approvals of its IceSense3 System, commercialization activities and the market opportunity for the Company's IceSense3 Cryoablation System in China. 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. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, many of which are beyond the control of the Company, including those set forth in the Risk Factors section of the Company's Registration Statement on Form F-1 (as amended, the "Form F-1") filed with the SEC. Copies of the Company's Form F-1 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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