April 5, 2021

IceCure Medical Granted FDA Breakthrough Device Designation for ProSense® Cryoablation System

- Treatment for patients with T1 invasive breast cancer and/or breast cancer for patients not suitable for surgical alternatives included in the indications being reviewed

CAESAREA, Israel, April 5, 2021 /PRNewswire/ -- IceCure Medical Ltd. (TASE: ICCM) ("IceCure" or the "Company"), developer of the next generation cryoablation technology that destroys tumors by freezing, announced today that it has been granted Designation as a Breakthrough Device from the U.S. Food and Drug Administration (FDA) for its lead asset, ProSense®, and proposed indication for use, including for use in the treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer. ProSense® is a liquid-nitrogen-based cryoablation system that enables minimally-invasive, treatment of cancer tumors.

The FDA Breakthrough Device Program is intended to help patients receive more timely access to medical devices that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide a priority review and feedback through development to commercialization. IceCure looks forward to this accelerated collaborative dialogue with the FDA to expedite the commercialization of ProSense® for the treatment of benign and malignant tumors.

Eyal Shamir, Chief Executive Officer of IceCure commented, "We are thrilled to receive the Breakthrough Device Designation from the FDA for our lead asset, ProSense®, based on promising clinical outcomes in multiple clinical studies to date. ProSense® has successfully demonstrated the potential to be an exceptionally safe and effective minimally-invasive cryoablation approach to tumor destruction. We believe receipt of this designation is a testimony to the potential of ProSense® to become the new gold standard for cryoablation tumor therapy."

Mr. Shamir continued, "The addition of the Breakthrough Device Designation builds on a series of successful regulatory milestones. ProSense® has already received FDA approval for general minimally-invasive cryoablation applications, including for kidney, liver, and benign breast tumors. IceCure is further pursuing FDA-specific approval for breast cancer with its ongoing ICE3 clinical trial, the largest controlled multilocation clinical trial in the U.S. for liquid nitrogen-based cryoablation of small, low-risk, early-stage malignant breast tumors. We are excited to have updated interim results of the ICE3 trial presented at the upcoming American Society of Breast Surgeons Annual Meeting on April 30."

"As we continue to evaluate ProSense® for the treatment of breast cancer tumors in our ICE3 clinical trial, we are grateful to the FDA's Breakthrough Device Program. The FDA's rapid approval process combined with its extensive feedback, leaves IceCure well-positioned for an expedited path towards breast cancer commercialization in the U.S. We are looking forward to continuing to work closely with the FDA to make ProSense® available to the breast cancer patients that can benefit from our minimally-invasive cryoablation solution," concluded Mr. Shamir.

As part of the Breakthrough Device Program, the Medicare Coverage of Innovative Technology (MCIT) program, which is pending approval by the Biden Administration, could provide national Medicare coverage for breakthrough-designated devices, such as the ProSense®, for a four-year duration starting on the day of the FDA marketing authorization. The Company will still be required to apply for CPT1 codes under regular approval procedures in order to receive reimbursement after the four-year provisional coverage period.

About IceCure Medical

Founded in 2006, Israel-based IceCure Medical (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 surgical alternative to tumor removal that is easily performed in a relatively short procedure. The system is marketed and sold worldwide, after receiving FDA and CE approvals. To learn more, please visit: www.icecure-medical.com.

Forward Looking Statements

The foregoing about completing the Transaction is Forward-Looking Information, as defined in the Securities Law, which depends on factors outside the Company's control, including the General Meeting's approval of the Transaction and receiving TASE's approval to list the securities for trading. In addition, the statements about listing the Company shares for trading on NASDAQ without the need for a concurrent public offering depend on factors that are outside the Company's control, including the Company meeting NASDAQ rules and provisions at the time of listing, market conditions, receiving the SEC's approval for the listing document and the document's entry into effect. In view of the foregoing, this information might not materialize or materialize significantly differently than described above.

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