September 5, 2023

IceCure Medical's ProSense Cryoablation System Receives Regulatory Approval in Brazil

- ***$6.6 million in sales expected in Brazilian market over the next five years per distribution agreement guarantees***
- ***High level of early interest in ProSense in South America's largest market***

CAESAREA, Israel, Sept. 5, 2023 /PRNewswire/ -- IceCure Medical Ltd. (Nasdaq: ICCM) ("IceCure" or the "Company"), developer of minimally-invasive cryoablation technology, the ProSense® System, that destroys tumors by freezing as an alternative to surgical tumor removal, today announced that its ProSense System has received regulatory approval as a Class III device from the Brazilian Health Regulatory Agency ("ANVISA"). ProSense's disposable cryoprobes and introducers, were previously registered as Class II devices by ANVISA. Applications for both the ProSense System and its disposable cryoprobes and introducers were submitted to ANVISA by IceCure's distributor in Brazil, Ktrfios Importação e Exportação LTDA ("Ktrfios").

ProSense's indications approved by ANVISA are oncology, which includes the ablation of benign and malignant tissues in the breast, prostate, kidney, lung, liver, musculoskeletal, and skin tissue, as well as for palliative intervention and other indications.

Healthcare providers are cleared to conduct procedures with ProSense, its introducers and disposable probes, and Ktrfios is cleared to both market and sell ProSense's introducers and disposable probes. ANVISA has assessed that the probes, which were initially registered as a Class II device under ANVISA rules, are to be transitioned to a Class III device and aligned with the Brazilian regulatory system classification for the same class as ProSense.

Therefore, ANVISA has requested that the probes also be submitted by Ktfrios for regulatory approval as a Class III device. The introducers remain a Class II device and do not require an additional regulatory submission. Class III device clearance for the probes is expected to be finalized by the end of the first quarter of 2024.

"We are very pleased that ProSense has received regulatory approval in Brazil. We expect this to translate into near-term revenues. Early indications of market interest point to strong demand in the largest market in South America where cost-effective, minimally invasive, safe, and effective cryoablation procedures can offer great benefits compared to traditional surgical interventions," stated IceCure Chief Executive Officer, Eyal Shamir.

With a total population of over 200 million people, more than 500,000 new cancer cases and more than 250,000 deaths attributed to cancer each year according to the World Health Organization's Cancer Tomorrow | IARC project, Brazil has an urgent need for minimally invasive cancer treatments.

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 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 and Israeli 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 Class III device clearance for the probes by the end of the first quarter of 2024; the expected near-term revenues as a result of regulatory approval of ProSense in Brazil; and the potential of ProSense to offer great benefits compared to traditional surgical interventions. 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 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.

IR Contact:

Email: investors@icecure-medical.com
Michael Polyviou
Phone: 732-232-6914
Todd Kehrli
Phone: 310-625-4462

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