

November 29, 2023



IceCure's ProSense® Deepens Regulatory Approval in India

- ***ProSense® is already marketed and sold in India based on previous regulatory requirements and now has been re-classified due to new regulations***
- ***Breast cancer cryoablation is already performed in India with ProSense®***

CAESAREA, Israel, Nov. 29, 2023 /PRNewswire/ -- [IceCure Medical Ltd.](#) (NASDAQ: ICCM) ("IceCure", "IceCure Medical" or the "Company"), developer of the ProSense® System, a minimally-invasive cryoablation technology that destroys tumors by freezing as an alternative to surgical tumor removal, today announced that the Central Drugs Standard Control Organization ("CDSCO") in India has granted approval for the ProSense® system based on the CDSCO's updated regulatory requirements. This is in addition to existing approvals, including disposables and cryoprobes, already approved for indications covering general surgery and oncology for tissues of the breast, lung, bone, kidney, liver and more. ProSense® was previously marketed and sold in India in accordance with prior regulatory requirements. This latest approval, granted in November 2023, confirms that ProSense® meets all updated regulatory requirements in India.



ProSense® is marketed and sold in India through IceCure's distributor, Novomed. The first breast cancer cryoablation procedure in India was conducted using ProSense® in June of 2023, at the Kovai Medical Center and Hospital in Coimbatore. Along with Novomed, IceCure recently presented ProSense® at the 10th Annual Conference of the Breast Imaging Society of India, where the cryoablation system was enthusiastically received by doctors, who attended a presentation of the ICE3 clinical study results and participated in hands-on demonstrations.

"India is a very important market for us because we see the potential for significant growth

with safe, effective, and cost-efficient technologies rapidly adopted. We have a highly productive partnership with our in-country distributor, Novomed, and anticipate increasing market traction," stated IceCure's Chief Executive Officer, Eyal Shamir. "Obtaining and maintaining regulatory approvals across the world supports our continued commercial traction worldwide."

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 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 statement in this press release when it discusses: the potential for significant growth and increasing market traction in India; and that obtaining and maintaining regulatory approvals supports the Company's continued commercial traction worldwide. 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, 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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