

October 11, 2022



# IceCure Medical's ProSense® Cryoprobes and Introducers Receive Regulatory Approval in Brazil

- ***Regulatory filing submitted by KTRFIOS, IceCure's distributor in Brazil***
- ***ProSense Cryoablation System approval in Brazil is pending***
- ***\$6.6 million in expected sales during the five years following full regulatory approval, per distribution agreement***

CAESAREA, Israel, Oct. 11, 2022 /PRNewswire/ -- [IceCure Medical Ltd.](#) (Nasdaq: ICCM) (TASE: ICCM) ("IceCure", "IceCure Medical" 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 Cryoprobes and Introducers have received regulatory approval from the Brazilian Health Regulatory Agency ("ANVISA"). The application was submitted in June 2022 by KTRFIOS IMPORTACAO E EXPORTACAO LTDA, IceCure's distributor in Brazil ("KTRFIOS").

The ProSense Cryoprobes and Introducers are disposable Class II devices, per ANVISA. Essential components of the ProSense System, Cryoprobes are inserted into the patient during the cryoablation procedure to freeze tumors, and Introducers provide access to the targeted tumor tissue. As the ProSense Cryoablation System is considered a Class III medical device, the application for it was filed separately with ANVISA and is currently pending approval.

"We are very pleased to achieve this first step in the path to receiving full regulatory approval in Brazil," stated IceCure CEO, Eyal Shamir. "Working with KTRFIOS has been highly productive, and we anticipate strong demand in Brazil upon the additional pending approval of the ProSense Cryoablation System."

IceCure's distribution agreement with KTRFIOS includes the guarantee of at least \$6.6 million in expected total sales during the five years following the full system's regulatory approval.

## About IceCure Medical

Israel-based IceCure Medical (Nasdaq: ICCM) (TASE: 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 to-date by FDA and approved in the European CE Mark.

## 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 anticipated demand for its ProSense Cryoablation System in Brazil after full regulatory approval and its expectation of \$6.6 million in total sales under its distribution agreement with KTRFIOS. 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, 2021 filed with the Securities Exchange Commission (the "SEC") on April 1, 2022, as amended, which is available on the SEC's website, [www.sec.gov](http://www.sec.gov). Copies are available on the SEC's website, [www.sec.gov](http://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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