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IceCure Announces Regulatory Filing Submission for Approval of ProSense® in Canada for Indications Including Ablation of Benign and Malignant Breast Tumors

Canadian hospitals and health care providers have expressed strong interest in ProSense® as they seek minimally invasive treatments for breast and other tumors

CAESAREA, Israel, July 25, 2022 /PRNewswire/ -- [IceCure Medical Ltd.](#) (NASDAQ: ICCM) (TASE: ICCM) ("IceCure" or the "Company"), developer of minimally-invasive cryoablation technology, the ProSense® System ("ProSense") that destroys tumors by freezing as an alternative to surgical tumor removal, today announced the submission of a regulatory filing with the Canadian governmental agency, Health Canada, for approval of IceCure's ProSense System and its cryoprobes for the treatment of numerous indications including:

- Oncology – ablation of benign and malignant breast tumors as well as benign and malignant tumors of the lung, liver, and musculoskeletal system, and for palliative intervention;
- Urology – ablation of renal cell carcinoma;
- Thoracic surgery – ablation of cancerous lesions in the lung tissue; and
- Other indications and for general surgery.

The ProSense System currently has regulatory approval for various indications in 14 countries, including in the U.S. and Europe.

According to statistics from the Canadian Cancer Society, an estimated [28,600](#) women will be diagnosed with breast cancer in Canada in 2022, while an estimated [30,000](#) people will be diagnosed with lung cancer. Furthermore, breast cancer is the most common cancer among Canadian women. About [1 in 8](#) women will be diagnosed with the disease in their lifetime.

"We have been contacted by multiple Canadian healthcare providers, including hospitals, with requests to purchase and implement ProSense for treating a range of indications, with malignant breast tumors being the most pressing need," stated IceCure CEO, Eyal Shamir. "We believe demand is being driven by a combination of ProSense's rising prominence in the global market and health care providers discovering, over the past two years during the pandemic, that they needed minimally invasive solutions that can be administered in an outpatient setting outside of an operating room. The benefits of minimally invasive procedures have become clearer than ever, driving demand in a post-pandemic environment. We hope to receive Health Canada's approval, further expanding ProSense's global regulatory and commercial footprint."

About IceCure Medical Ltd.

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 the U.S. Food and Drug Administration and approved in Europe with the 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 statements in this press release when it discusses its regulatory approval process in Canada, potential collaboration with prospective Canadian healthcare providers, the demand for ProSense System in Canada and around the world, expanding IceCure's global regulatory and commercial footprint and the benefits of minimally invasive medical procedures. 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, which is 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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