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IceCure Receives FDA Clearance for Expanded Indications of Cryoablation Technology and Regulatory Approval of New MultiSense System; Plans to Increase U.S. Presence and Operations

Expands Use of Cryoablation Technology to Treat Liver and Kidney Tumors

CAESAREA, Israel, Jan. 7, 2020 /PRNewswire/ -- Following the additional U.S. Food and Drug Administration (FDA) clearance for its Cryoablation Technology, IceCure Medical Ltd. (TASE: ICCM), an Israeli medical device company, developers of a non-surgical Liquid Nitrogen (LN2) cryoablation technology to destroy benign and cancerous tumors by freezing, plans to significantly extend its U.S. operations in target markets for indications with existing CPT codes and reimbursement. The new FDA clearance will enable the Company to market its solution for the treatment of cancerous and benign tumors of the Kidney; Liver; Ear, Nose and Throat (ENT); and further neurology indications.

"The additional FDA clearance is a pivotal milestone for IceCure and we now plan to expand our operational capabilities in the addressable markets for labels with existing CPT codes and reimbursement, while driving further revenues," commented Eyal Shamir, CEO of IceCure Medical. "Receipt of this bundled approval is a significant step in our ability to commercialize our products in the U.S., and we believe this along with the other achievements, allow us to enter 2020 with plenty of momentum and revenue generation opportunities."

The new 510K clearance broadens IceCure's previous general FDA approval, and allows the Company to market, advertise and sell its advanced non-surgical cryoablation products for the treatment of new specific indications. This is particularly beneficial for the treatment of kidney and liver tumors where there is already existing CPT codes and reimbursement. Additionally, the approval includes clearance for its new MultiSense system, which will allow treatment with three needles in unison. Not only does this will help to reduce the length of procedures, it will also be highly advantageous in improving the treatment of multiple tumors as well as for larger masses. The general approval previously given to its IceSense3 system enabled one needle treatment that was ideal for small tumor masses. The new approval given relates to all of the company's cryoablation systems (IceSense3™, ProSense™ and MultiSense), including its accompanying products (needles and accessories) and software updates.

The additional FDA approval follows several recent key achievements:

- Received an order to supply systems and needles to freeze breast cancer tumors for an independent trial by a leading Chinese hospital
- Initial registration to market the Company's probes in China
- Regulatory approval in Thailand
- Entered into a a strategic agreement with the leading global Japanese medical device company, Terumo Corporation (Tokyo: 4543) (TRUMY: OTC US), for a minimum of US $13.2 million.
- Sharon Levita, a medical device veteran and former CFO of Mazor Robotics, joined the Company's Board of Directors. M. Levita brings extensive financial and business management experience in developing successful companies
- CPT III code approved by the American Medical Association (AMA) to support further adoption of IceCure's minimally invasive cryoablation treatments for breast cancer

The Company's Chief Executive Officer, Eyal Shamir and Chief Financial Officer, Ronen Tsimerman, will be meeting investors in San Francisco on Monday and Tuesday, January 13th and 14th. Investors and analysts should contact Michael Polyviou at mpolyviou@evcgroup if they would like to schedule a one-on-one meeting.

About IceCure Medical

Founded in 2006, IceCure Medical (TASE: ICCM) is an Israeli medical device company that develops and markets an advanced liquid-nitrogen-based cryoablation therapy for women's health and the interventional oncology market, with the primary focus areas being breast, kidney and lung cancer. Its technology is a safe, effective, non-invasive alternative to surgical tumor removal that is easily performed in a short procedure. The system has US FDA 510k and CE Mark clearance and is sold worldwide. The company has a wholly-owned subsidiary in the United States, IceCure Medical Inc., with offices in New Jersey. To learn more, please visit: www.icecure-medical.com.

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