IMRICOR RECEIVES ETHICS COMMITTEE APPROVAL FOR VISABL-VT AND COMPLETES FIRST-IN-HUMAN EVALUATION OF NORTHSTAR-MR 3D MAPPING SYSTEM

Highlights:

- Leipzig Heart Centre Ethics Committee has approved the VISABL-VT clinical trial. The trial submission now advances to the German Federal Institute for Drugs and Medical Devices (BfArM) for final approval, upon which the trial can commence.

- First-in-human use of the Company's NorthStar-MR 3D Mapping System prototype has been successfully completed at Haga Hospital, The Hague, Netherlands.

14 December 2022 – Minneapolis, MN United States (**15 December 2022** – Melbourne, Australia) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**), the global leader in real-time iCMR cardiac ablation products, is pleased to provide the following business update.

VISABL-VT Ethics Committee Approval

The Company has received the first of two required approvals to commence the "**Vis**ion-MR **Abl**ation of **VT**" or VISABL-VT clinical trial.

The Ethics Committee of the Leipzig Heart Centre approved the VISABL-VT trial, which is designed to study the treatment of ventricular tachycardia (VT) with real-time iCMR cardiac ablation. The next and final step required to commence the trial is to receive approval from the German Federal Institute for Drugs and Medical Devices (BfArM). Under the new European Medical Device Regulations (EU-MDR) regime, BfArM will not begin a review of a clinical trial until they receive a positive approval from a local Ethics Committee, which VISABL-VT has successfully received.

VISABL-VT is a prospective, single-arm, multi-centre interventional investigation of the safety and efficacy of radiofrequency (RF) ablation of ventricular tachycardia associated with ischemic cardiomyopathy performed with the Vision-MR Ablation Catheter 2.0 in the iCMR environment. The study calls for treating 64 patients and includes a 6-month follow-up for each patient, as is typical.

Imricor's Chair and CEO, Steve Wedan, commented: "*We were very pleased to receive the approval from the Ethics Committee in Leipzig. With this, our regulatory submission package has been validated, and we look forward with great anticipation to similarly receiving approval from BfArM, allowing us to commence the clinical trial*."

NorthStar-MR First-in-Human Experience

The team at Haga Hospital in The Hague, Netherlands successfully treated two atrial flutter patients in the iCMR this week with the Company's products, while simultaneously evaluating the Imricor's prototype **NorthStar-MR 3D Mapping System**. These procedures were the first human clinical procedures for which NorthStar-MR was evaluated.

The electrophysiologist who performed the procedures, Dr. Hemanth Ramanna, commented afterwards: "*This was amazing! NorthStar-MR has bridged gap between the experience that 3D mapping systems provide and additional benefits MRI provides. It's really fantastic. This going to change the way we do cases.*"

NorthStar-MR currently operates with Siemens MRI scanners, and it is the Company's goal to include NorthStar-MR as a supplement to the VISABL-VT trial submission, such that Siemens iCMR sites can participate in the trial. It is also the Company's goal to apply NorthStar-MR to MRI systems from GE Healthcare and Philips, ultimately providing the same user experience for physicians no matter which MRI platform they utilise.

NorthStar-MR is extremely significant to Imricor, as it removes the reliance on others to develop 3D mapping systems needed for complex ablation procedures, and it puts control of the Company's timelines back in Imricor's hands.

Imricor background and strategy

Imricor is leading the new field of *real-time iCMR cardiac ablations* – that is, cardiac ablations guided by real-time magnetic resonance imaging (MRI), rather than by conventional x-ray fluoroscopy. iCMR (*interventional cardiac magnetic resonance*) is the term used to describe such interventional procedures performed in conjunction with MRI. The goal is to provide faster, safer, and more effective treatments of cardiac arrhythmias compared to conventional means.

Imricor is the only company in the world that provides MRI-compatible consumable devices, such as single-use ablation catheters, required to perform cardiac ablations in an iCMR lab.

Benefits of real-time iCMR cardiac ablations are derived from the superior imaging capabilities of MRI compared to x-ray, especially when it comes to imaging the heart and vascular structures which are largely invisible to x-rays. Real-time iCMR also reduces repeated exposure to dangerous x-ray radiation.

Imricor's strategy to grow the field of real-time iCMR cardiac ablations worldwide is built on two actions: to increase the number of iCMR sites across the world and to increase the number of procedures doctors can perform at each iCMR site using Imricor's consumable products. The VISABL-VT clinical trial is a key driver of both strategic initiatives.

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Authorised for release by Steve Wedan, Executive Chair, President, and CEO.

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About Imricor

Imricor Medical Systems, Inc. (ASX:IMR) is a leading developer of innovative MRI-compatible medical devices which can be used to carry out real-time iCMR cardiac ablation procedures. Headquartered in the US, Imricor seeks to make a meaningful impact on patients, healthcare professionals, and healthcare facilities around the world by increasing the success rates and bringing down the overall costs of cardiac ablation procedures.

Imricor's Products

Imricor is a pioneer and leader in developing MRI-compatible products for cardiac catheter ablation procedures, and believes it is the first company in the world to bring commercially viable and safe MRI-compatible products to the cardiac catheter ablation market.

The Vision-MR Ablation Catheter is the Company's prime product offering, specifically designed to work under real-time MRI guidance, with the intent of enabling higher success rates along with a faster and safer treatment compared to conventional procedures using x-ray guided catheters. The Vision-MR Ablation Catheter has been approved in the European Union with an indication for treating type 1 atrial flutter. Imricor intends to seek approval for expanded indications in the future. The Company is also in the early stages of pursuing the required regulatory approvals to place its key products on the market in Australia and the U.S.

The Company has also obtained approval within the EU for the sale of the Advantage-MR EP Recorder/Stimulator System and its consumable product, the Vision-MR Dispersive Electrode.

Imricor sells its capital and consumable products to hospitals and clinics for use in Interventional Cardiac Magnetic Resonance Imaging (iCMR) labs, in which ablation procedures using the Vision-MR Ablation Catheter can be performed. An iCMR lab is an interventional lab that is fitted with MRI equipment for use in cardiac diagnostic and interventional procedures. The installation of iCMR labs is driven primarily by MRI equipment vendors working collaboratively with Imricor. Vendors such as Koninklijke Philips N.V. and Siemens Healthcare GmbH help to target certain sites and support the design and construction of iCMR labs for those sites.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on the Company's management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These include, without limitation, EU commercial market acceptance and EU. sales of our product as well as our expectations with respect to our ability to develop and commercialise new products. Management believes that these forward-looking statements are reasonable when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Imricor does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Imricor may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.