



## IMRICOR SUBMITS FOR APPROVAL TO COMMENCE VT TRIAL IN EUROPE

**19 September 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 announce that the Company has submitted for approval to commence a real-time iCMR-guided ventricular tachycardia (VT) ablation clinical trial.

The name of the study is “**Vision-MR Ablation of VT**” or VISABL-VT.

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.

The application for approval to commence VISABL-VT was submitted to the Ethics Committee at the Leipzig Heart Centre (the lead clinical site) as well as the German Federal Institute for Drugs and Medical Devices (BfArM), the German Competent Authority. Both submissions took place on September 15<sup>th</sup>. The Ethics Committee review will happen first, followed by a review by the Competent Authority. Upon approval by both regulating bodies, the trial will commence.

Additional submissions will follow as new sites are added to the study.

Imricor’s Chair and CEO, Steve Wedan, commented: “This is a major milestone for Imricor that brings us one monumental step closer to treating ventricular tachycardia with ablation procedures guided by real-time iCMR.

“Since this is our first clinical trial submission under the new Medical Device Regulations in Europe, we do not have a clear estimate of how long the approval process will take, but we are hopeful that we can begin enrolment before the end of the year.”

### **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 VT clinical trial is a key driver of both strategic initiatives.

## ENDS

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.

### Foreign Ownership Restrictions

Imricor's CHESS Depository Interests (**CDIs**) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (**Securities Act**) for offers which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. As a result of relying on the Regulation S exemption, the CDIs are 'restricted securities' under Rule 144 of the Securities Act. This means that you are unable to sell the CDIs into the US or to a US person for the foreseeable future except in very limited circumstances after the expiration of a restricted period, unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a 'FOR US' designation on the Australian Securities Exchange (**ASX**). This designation restricts any CDIs



from being sold on ASX to US persons. However, you are still able to freely transfer your CDIs on ASX to any person other than a US person. In addition, hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

### **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.