

# IMRICOR RECEIVES ETHICS APPROVAL TO COMMENCE VISABL-VT TRIAL

# **HIGHLIGHTS:**

- Imricor granted approval for VISABL-VT trial from the Medical Ethics Review Committee, Leiden The Hague Delft (METC LDD) to begin the trial at Haga Hospital in The Hague
- Approval paves the way for the trial to commence, targeting mid-August following physician and medical staff summer holidays

**31 July 2023** – Minneapolis, MN United States (**1 August 2023** – 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 it has received approval from the Medical Ethics Review Committee, Leiden The Hague Delft (METC LDD) to begin the VISABL-VT trial at Haga Hospital in The Hague, Netherlands.

The VISABL-VT trial is a prospective, single-arm, multi-centre investigation of the safety and efficacy of radiofrequency (RF) ablation of ventricular tachycardia (VT) 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 six-month follow-up for each patient. The study is intended to support CE mark certification of the Vision-MR Ablation Catheter 2.0 for treating VT.

The first patient to be enrolled in VISABL-VT is identified, and the first procedure is expected to take place in mid-August, upon the return of physicians and medical staff from summer holiday.

Imricor's Chair and CEO, Steve Wedan, commented: "This is an extraordinary milestone for Imricor.

"Since founding the Company 17 years ago, the goal has always been to develop technology that enables complex cardiac arrhythmias like ventricular tachycardia (or VT) to be treated utilising real-time 3D MRI (which we call interventional cardiac magnetic resonance, or iCMR) for guidance. We believe real-time 3D MRI imaging can add tremendous value to VT ablations in terms of effectiveness, time savings, and cost – all in an environment that is free of ionising radiation.

"Imricor continues to do what no one else has ever done before, and virtually everyone in the Company has worked tirelessly to make this extraordinary milestone possible. I want to especially acknowledge the clinical and regulatory teams led by our Director of Clinical Research, Dr. Katherine Lindborg, PhD, and our VP of Regulatory and Quality, Jennifer Weisz."

# **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.

#### **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.