IMRICOR SUBMITS NORTHSTAR FOR CE MARK APPROVAL AND ACCELERATES US APPROVAL PROCESS FOLLOWING STRONG INTEREST

Highlights:

- **Imricor has submitted NorthStar 3D Mapping System for CE Mark approval in Europe. This is the last step before commercial rollout of NorthStar across existing and new customer sites in Europe and, shortly thereafter, the Middle East**
- **Strong interest from US hospitals, even beyond cardiac ablations, has resulted in Imricor accelerating the 510k submission of NorthStar for FDA approval. Consumable product PMA approvals from FDA are expected in the second half of 2025**
- **NorthStar approval will allow for an installed base in the US to be established sooner and support a faster US launch following full FDA approval of the consumable ablation devices.**
- **VISABL-VT has received Ethics approval at Amsterdam UMC paving the way for the first MRI guided VT ablation procedure in the world.**

23 December 2024 – Melbourne, Australia (**22 December 2024** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) is pleased to provide an update on various advancements on regulatory progress in Europe and the US.

NorthStar Acceleration

Imricor is pleased to announce that it has submitted the NorthStar 3D Mapping System for CE mark certification in Europe. Upon receiving CE mark certification, NorthStar will be launched commercially across the EU and, shortly thereafter, the Middle East.

Imricor's NorthStar 3D Mapping System is considered to be a critical component to any interventional MRI program. Originally, the MRI scanner manufacturers were planning to develop and release their own mapping systems, each for their individual platforms, but a shift in strategy in 2022 across all partners has resulted in Imricor developing the NorthStar 3D Mapping System as a cross-platform MRI vendor-neutral mapping system, which is globally unique.

Given Imricor's ownership and control of NorthStar, Imricor will release and continually develop the mapping system at pace, adding modules and delivering the interventional guidance tools which customers desire. Early work with NorthStar across research sites has resulted in overwhelming demand for the system and has made it a de facto prerequisite for new sites. Inbound interest for NorthStar also goes beyond cardiac ablations, as sites would like to use it for other interventional MRI applications.

For these reasons, the Company believes NorthStar's release in the EU is a top priority, and that its US approval and release should also be prioritised above the approval and release of the Company's consumable ablation tools. This allows for faster EU iCMR lab adoption and earlier US iCMR lab adoption, providing a larger installed base for the Company's ablation tools sooner.

As a result of the acceleration of NorthStar's approval processes in Europe and the US, Imricor expects the full set of consumable ablation tools to receive FDA approval in the 2H of 2025.

VISABL-VT Update

The first-in-human Ventricular Tachycardia (VT) ablation guided by real-time MRI will take place shortly after the New Year, kicking off the VISABL-VT clinical trial. As announced during the Company's Q3 2024 investor briefing, the Ethics Committee at Amsterdam UMC needed to review last-minute changes to a 3rd party partner's defibrillator. That review is complete, Ethics approval has been received, and the trial can now begin; however, due to the holiday period there is no longer enough time to commence the first procedure before year end.

Dr Marco Götte, Cardiologist and Director of Amsterdam UMC's Cardiac MRI Research Team, commented: "Complex ablations guided by MRI was what I originally had in mind when we started working with Imricor many years ago. It has been fascinating to start our program with atrial flutter, but now we are ready to take the important next step.

"While we have been waiting for ethics approval to begin performing complex ablation procedures such as VT, I have used the time to develop new MRI imaging techniques including new pulse sequences. I even travelled to Minneapolis recently to spend three days over a weekend in Imricor's iCMR lab, refining the imaging protocols and NorthStar workflow for the first VT procedure. This is groundbreaking work which I think will signal a major shift in the standard of care as it relates to complex arrhythmia treatment."

Imricor's Chair and CEO, Steve Wedan, added: "Like all of us, I wanted to do our first VT procedure in 2024, and I look forward with great anticipation to that ground-breaking procedure in early 2025.

"Reflecting on the outstanding year we have had, our FDA process is progressing, new sites are coming on board in the EU and Middle East, and we have been extremely pleased with the strong demand for our NorthStar 3D Mapping System to become available as soon as possible.

I believe the prioritisation of NorthStar ahead of the consumable ablation tools makes perfect sense. With NorthStar in market in Europe and the Middle East, we make it much easier for our sales team to establish new labs and grow our installed base and procedure volume. In addition, NorthStar will pave the way in the US for our ablation tools by allowing us to grow our installed base here as well. NorthStar provides value to sites for other interventional procedures beyond ablation, and NorthStar captures the imagination of our customers and future customers, sparking so many new ideas for what we can add to future iterations to grow its utility and value.

"With our sales team growing all over the world, and our focus on making all products available to our customers as soon as possible, we are accelerating toward our end goal of delivering the power of MRI guidance to interventional procedures and ultimately changing the standard of care."

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

Media and Investor Relations Contacts:

Simon Hinsley
Executive Director, NWR
simon@nwrcommunications.com.au
+61 401 909 653

Nick Corkill
VP Corporate Strategy, Imricor
nick.corkill@imricor.com
+61 450 475 633

About Imricor

Imricor Medical Systems, Inc. (ASX:IMR) is striving to make interventional medical procedures better, safer, and more cost effective by making it possible for these procedures to be performed under real-time magnetic resonance imaging (MRI) guidance, rather than under x-ray fluoroscopy guidance, thus taking advantage of MRI's superior imaging capabilities.

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, the Kingdom of Saudi Arabia (KSA), and New Zealand with an indication for treating type 1 atrial flutter. Imricor intends to seek approval for expanded indications in the future. The Company is also pursuing the required regulatory approvals to place its key products on the market in the U.S. and the other Middle East countries.

The Company has also obtained approval within the EU for the sale of the Advantage-MR EP Recorder/Stimulator System and other consumable products, such as the Vision-MR Diagnostic Catheter and 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., Siemens Healthcare GmbH, and GE HealthCare help to target certain sites and support the design and construction of iCMR labs for those sites.

Foreign Ownership Restrictions

Imricor's CHESS Depositary 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.