IMRICOR RECEIVES CE MARK APPROVAL FOR 2ND GENERATION VISION-MR ABLATION CATHETER

Highlights:

- **2nd generation Vision-MR Ablation Catheter receives CE mark certification under new more stringent European MDR regime**
- **Imricor's manufacturing certificate updated to include MDR compliance**
- **Imricor expects to submit new MDR-compliant 2nd generation Vision-MR Ablation Catheter for TGA approval in Australia**

19 February 2025 – Melbourne, Australia (**18 February 2025** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) is pleased to announce that the 2nd generation Vision-MR Ablation Catheter has received CE mark certification under the new, more stringent, European Medical Device Regulation (MDR), for the treatment of type 1 atrial flutter (AF).

The 2nd generation Vision-MR Ablation Catheter is the catheter involved in both the VISABL-VT clinical trial in Europe and the VISABL-AFL clinical trial supporting FDA approval in the US.

The Company has received the final approval certificate to enable manufacturing of the 2nd generation Vision-MR Ablation Catheter under MDR, following an on-site audit conducted by Imricor's Notified Body in October 2024.

With the successful CE mark certification under MDR, the Company expects to submit the 2nd generation Vision-MR Ablation Catheter for approval by the Australian Therapeutic Goods Administration (TGA).

Imricor's Chair and CEO, Steve Wedan, commented: "The 2nd generation Vision-MR Ablation Catheter incorporates performance and cost improvements developed by Imricor's engineers over the past decade, and is designed to be our future ablation catheter globally.

"Achieving CE mark under the more challenging MDR regime for our flagship consumable device, the 2nd generation ablation catheter, is a very positive sign that speaks volumes about the quality and robustness of our design, manufacturing, quality system, and regulatory team."

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 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 and KSA for the sale of the Advantage-MR EP Recorder/Stimulator System and other consumable products, such as the Vision-MR Diagnostic Catheter (pending in KSA) 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.