



IMRICOR RECEIVES CE MARK APPROVAL FOR ADVANTAGE-MR UNDER EUROPEAN MEDICAL DEVICE REGULATION (MDR)

Highlights:

- Imricor receives CE Mark certification for the Advantage-MR system under new European Medical Device Regulation (MDR)
- Approval follows CE Mark certification for the 2nd generation Vision-MR Ablation Catheter in February of 2025

17 April 2025 – Melbourne, Australia (**16 April 2025** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)** is pleased to announce that the Company's Advantage-MR EP Recorder/Stimulator (**Advantage-MR**) has received CE mark certification under the European Union's new Medical Device Regulation (MDR).

This follows the earlier CE mark approval of Imricor's 2nd generation Vision-MR Ablation Catheter under the MDR regime, as announced on 19 February 2025.

Commercial launch of the 2nd generation Vision-MR Ablation Catheter and the new Advantage-MR system is planned to commence in June across new and existing sites in the EU.

Imricor's Chair and CEO, Steve Wedan, commented: "As of today, our entire commercial product portfolio in Europe is approved under MDR. This was a huge undertaking over the past several years to transition from the old European Medical Device Directive rules to the new, more stringent Medical Device Regulations.

"Our Vice President of Regulatory and Quality, Jennifer Weisz, has built a world-class team, and that team continues to deliver approvals for multiple products across multiple geographies, all with varying regulations and requirements.

"During this regulatory transition, we also took the opportunity to significantly improve our Vision-MR Ablation Catheter, and early feedback from physicians who have used the new 2nd generation catheter in our VISABL-AFL and VISABL-VT clinical trials has been very positive, noting improved manoeuvrability characteristics and robustness. We will soon commence phasing out the 1st generation products from the market, replacing them with these new MDR CE mark approved devices."

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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 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 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 CHES 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.