



IMRICOR RECEIVES CE MARK APPROVAL FOR NORTHSTAR

Highlights:

- **CE mark approval secured under new more stringent EU MDR framework**
- **First software-centric product approval globally for Imricor**
- **Approval received ahead of Company's schedule**
- **Enables a staged commercial launch across Europe and the Middle East**
- **Foundation for future growth: NorthStar is considered the central software layer and guidance system for a broad pipeline of existing and future MRI-guided procedures**

10th June 2025 – Melbourne, Australia (**9th June 2025** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)** is pleased to announce that it has received CE Mark certification under the European Union's Medical Device Regulation (**EU MDR**) for its NorthStar Mapping System (**NorthStar**).

NorthStar is approved as a Class IIa medical device under EU MDR. The system comprises a computer workstation and a software application, making it Imricor's first commercial software-centric product globally.

This milestone significantly strengthens Imricor's position as the market leader in interventional cardiac MRI (iCMR) and broadens the Company's offerings across Europe and the Middle East.

Imricor's Chair and CEO, Steve Wedan, commented: "Achieving CE Mark approval for NorthStar under EU MDR represents a transformative step towards establishing a global platform for MRI-guided interventions. I often say that NorthStar's purpose is to transform MR imaging from something analogous to taking a picture with a still camera into something analogous to shooting a live video. When you're guiding a medical procedure with MRI, you need 'live video' capabilities.

"We expected NorthStar's CE mark approval mid-year, and we were pleased to receive it earlier than anticipated. But this is more than just a regulatory win. It's the launch of our software era, and as we grow and expand interventional MRI applications even beyond cardiac ablations, I envision NorthStar growing and expanding to become the central hub of every interventional MRI practice."

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 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 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.