IMRICOR SUBMITS SECOND MODULE TO FDA

Highlights:

- **The second module for the Company's Premarket Approval (PMA) products has been submitted to the FDA**
- **Module two comprises manufacturing processes across seven devices**
- **Following successful submission of module one, the second module has also been submitted inside expected timelines**
- **NorthStar, Imricor's 3D mapping and guidance system, will be submitted next under the 510(k) process, following NorthStar's recent submission for CE Mark approval.**

4 March 2025 – Melbourne, Australia (**3 March 2025** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) is pleased to announce that it has submitted the second Premarket Approval (PMA) module for FDA review.

The second module covers the design, manufacturing, and quality processes surrounding seven products in total. Six of these are the Company's products which are undergoing the FDA's PMA approval process, with an additional 3rd party product Imricor will distribute. This module includes items such as design controls, receipt, inspection and storage of raw materials, build procedures, process validation, part and device traceability, along with the applicable quality management systems. As such, the scope of the manufacturing module is significant.

Imricor is executing a modular review process with the FDA, whereby modules covering various aspects of the Company's products are submitted and reviewed serially, with the goal achieving a more streamlined review process. In the background, the team have been working on the next PMA module, as well as the NorthStar 510(k) FDA application slated for submission next. NorthStar will follow a 510(k) pathway which involves a shorter review cycle, and Imricor expects to have this product commercially available in the US market in early Q3. The commercial launch in Europe is expected around the middle of the year.

Imricor's Chair and CEO, Steve Wedan, commented: "We had set an internal deadline for the manufacturing module to be submitted by the end of February, and the team came through again, keeping us on track.

"It is difficult to convey how much work is involved due to the number of devices for which we are seeking approval simultaneously. We are now one step closer to getting the entire platform of technology on the market in the US. Again, I commend our Regulatory team, as well as our Quality and Manufacturing teams for this tremendous milestone. We look forward to working closely with the FDA as we continue towards full submission and market entry.

"The Company remains on track for the submission of the remaining modules in line with its planned timeline and will continue to update the market on further developments."

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.