IMRICOR REGULATORY UPDATE

Highlights:

- **FDA review of Imricor's first module completes successfully, exceeding timeline expectations**
- **In Europe, approval of the Vision-MR Ablation Catheter 2.0 is awaiting only final certification following a successful on-site audit**
- **Changeover to the new more stringent Medical Device Regulations in the EU is progressing smoothly and faster than anticipated**

14 October 2024 – Melbourne, Australia (**13 October 2024** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) provides the following update on several regulatory initiatives supporting new device approvals in the US and Europe.

US Regulatory Milestones

On June 29th, the Company submitted the first Premarket Approval (PMA) module for FDA review. The submission covered devices including the Vision-MR Ablation Catheter 2.0 and RF-5000 Ablation Generator, Irrigation Pump, Tubing Set, and Remote Control Unit. The module content included pre-clinical animal study data, biocompatibility, and sterilisation validation. These can often be the most difficult topics for review, and they can take the longest, which is why they were submitted first.

On September 27th, the Company was pleased to receive notice from the FDA that the module is accepted and considered closed. With this module complete, Imricor has achieved a major milestone toward FDA approval.

EU Regulatory Milestones

On October 1st and October 2nd, Imricor's Notified Body, TÜV SÜD, conducted an on-site Audit of Imricor's facilities. There were several purposes for the audit, including:

- Medical Device Directive (MDD) and Medical Device Regulation (MDR) adherence surveillance
- MDR review for the design controls and manufacturing of the Vision-MR Ablation Catheter 2.0 and Advantage-MR EP Recorder/Stimulatory System

In summary, the audit results were positive, and the Company will be recommended for certification to manufacture these products under the new more stringent MDR regime.

Earlier this year, the MDR technical review of the Vision-MR Ablation Catheter 2.0 was completed successfully, meaning only the final certification is required to begin manufacturing and selling the device. At this time, the new 2.0 catheter will be phased in to replace the original Vision-MR Ablation Catheter in the market.

Along with the new 2.0 catheter, the Advantage-MR system must also be approved under MDR. The first round of that technical review is complete, and the Company received positive feedback on the overall technical documentation from TÜV SÜD. The Company will respond to questions by October 18th, and the commercial launch of the new MDR Advantage-MR system is expected in Q1 2025, ahead of Imricor's original projections.

This audit and technical review combine to ensure that Imricor can continue selling devices under the old MDD regime and the Company is closing in on the release of the 2.0 catheter, as well as its changeover to MDR compliance.

Imricor's Chair and CEO, Steve Wedan, commented: "Understanding that this is a lot of technical regulatory information, let me put it in context. The FDA review process for our first module went very smoothly and in a time frame that exceeded our own expectations. That's not to say there won't be challenges in the other module reviews, but this was a challenging module, and we are very pleased with FDA's punctuality and efficiency.

"In addition, we are navigating the process of approval for the Vision-MR Ablation Catheter 2.0 under the new MDR regime with success and with timelines that also exceed our original expectations. Importantly, the 2.0 catheter is the one used in the VISABL-VT and VISABL-AFL trials, so everything is coming together nicely worldwide.

"It's hard to overstate how impressive this all is (especially for an industry insider), and it is only possible because of Imricor's world-class Quality and Regulatory teams, formed and operating under the equally impressive leadership of our Vice President, Jennifer Weisz."

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 a leading developer of innovative MRI-compatible medical devices which can be used to carry out real-time iCMR cardiac ablation procedures. Headquartered in the US, Imricor seeks to make a meaningful impact on patients, healthcare professionals, and healthcare facilities around the world by increasing the success rates and bringing down the overall costs of cardiac ablation procedures.

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.