IMRICOR PAUSES TGA PROCESS TO WAIT FOR SECOND-GENERATION VISION-MR ABLATION CATHETER

Highlights:

- **Imricor has withdrawn its application for TGA approval of the first-generation Vision-MR Ablation Catheter**
- **The second-generation Vision-MR Ablation Catheter is expected to be released in 2025 across Europe, the Middle East, and the US, while the first-generation version is phased out of production**
- **The Company may submit for TGA approval of the second-generation Vision-MR Ablation Catheter, upon completion of the VISABL-AFL clinical trial supporting US FDA approval**
- **No material impact on Imricor's mid-term or long-term revenue potential is anticipated**

13 August 2024 – Melbourne, Australia (**12 August 2024** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) announces today that it has withdrawn its application to the Australian Therapeutic Goods Administration (**TGA**) for approval of the first-generation Vision-MR Ablation Catheter.

The Company plans to complete the VISABL-AFL trial to support United States Food and Drug Administration (**FDA**) approval of the *second-generation* Vision-MR Ablation Catheter (**Gen 2**), and potentially subsequently submit to TGA for approval of the Gen 2 catheter.

The Company does not anticipate a material impact on mid-term or long-term revenue potential.

Imricor's Chair and CEO, Steve Wedan, commented: "Our plan is to sunset the manufacturing of the first-generation Vision-MR Ablation Catheter as soon as the Gen 2 catheter is approved in Europe and the Middle East. The Gen 2 catheter has already received its CE mark device certificate in Europe under the new more stringent Medical Device Regulations, and we are only awaiting the next in-house audit of our quality system to expand the scope of our manufacturing site certificate.

"Given the timing, makes more sense to wait a few months, complete the VISABL-AFL trial, and possibly submit the Gen 2 catheter to TGA alongside our submission for United States FDA approval. That way, Australian doctors would not find themselves one generation behind, and we would not need to continue manufacturing the first-generation catheter only for Australia.

"Australia is not a material market for Imricor from a revenue standpoint, but we are excited to bring doctors and patients the benefits of MRI-guided ablations in a market where many of the Company's investors reside. Imricor has regulatory approval in New Zealand, and we will focus our ANZ efforts in this market in the short term."

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 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.