ASX Announcement

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IMRICOR SUBMITS SECOND GENERATION ABLATION CATHETER FOR APPROVAL IN EUROPE

Highlights

- **New catheter has been designed to support current ablations as well as future indications including ventricular tachycardia (VT)**
- **The submission, which was completed as scheduled, allows regulatory review to occur in parallel with VT clinical trial as planned**

Imricor Medical Systems, Inc. (**Company** or **Imricor**) (**ASX:IMR**), the global leader in realtime iCMR cardiac ablation products, is pleased to announce it has submitted its second-generation Vision-MR Ablation Catheter for CE mark certification with the Company's European Notified Body.

This is a significant and critical step in meeting the Company's strategic goal of gaining approval for ventricular tachycardia (VT) ablations as planned. Next steps along the path to VT indications include applying for approval to commence a European clinical study aimed at demonstrating the safe and effective use of Imricor's products for VT ablations, followed by performing the VT clinical trial, which is expected to begin later this year.

The second-generation Vision-MR Ablation Catheter was submitted for the initial indication of treating Type 1 atrial flutter (AFL), relying on the previous clinical trial results of the first-generation catheter. The Company is expecting a 12-month review cycle for the new catheter. While it is under regulatory review, it will be used in the VT clinical trial, such that once the clinical trial is completed, data can be submitted for further review to expand the catheter's indications to VT.

The second-generation Vision-MR Ablation Catheter is expected to replace the first-generation Vision-MR Ablation Catheter upon approval.

Imricor's Executive Chair and CEO, Steve Wedan, said: "This is yet another major milestone on our path to VT ablations performed in the iCMR lab. Nothing is more important to our business, than delivering iCMR-guided VT ablations to the clinical world.

"Our second-generation ablation catheter has been in development for many years, and its submission is a monumental task and a huge accomplishment for the entire Imricor team.

"We expect this Vision-MR Ablation Catheter to be the catheter of the future, applied to iCMR guided ablations of AFL, as well as VT and atrial fibrillation (Afib), once we conduct clinical trials for the latter indications.

"In addition, the second-generation Vision-MR Ablation Catheter is the catheter we will bring to market in the US. It is the catheter that we included in our Investigational Device Exemption (IDE)

application with the US FDA. We expect to receive IDE approval this calendar year, which allows Imricor to conduct a clinical trial in the US and grow our geographical footprint."

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 MRI-guided cardiac catheter 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 catheter 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 with an indication for treating type 1 atrial flutter. Imricor intends to seek approval for expanded indications in the future. The Company is also in the early stages of pursuing the required regulatory approvals to place its key products on the market in Australia and the U.S.

The Company has also obtained approval within the EU for the sale of the Advantage-MR EP Recorder/Stimulator System and its consumable product, the 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. and Siemens Healthcare GmbH 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.