



## **ASX Announcement**

### **MIRTLE SALES AGREEMENT SUPPLEMENTARY INFORMATION AND BUSINESS UPDATE**

**29 September 2021 – Minneapolis, United States – Imricor Medical Systems, Inc. (Company or Imricor) (ASX:IMR)** the global leader in MRI-guided cardiac ablation products, provides the following business update.

#### **MiRTLE Sales Agreement Supplementary Information**

Further to the announcement released to the ASX on 28 September 2021, Imricor provides the following supplementary information in relation to the MiRTLE sales agreement (Agreement).

The initial term of the Agreement starts immediately and runs for an initial term of five years, automatically renewing for one-year periods thereafter unless terminated by either party with 12-months' notice.

The Agreement covers any location where the MiRTLE system has regulatory approval for sale. The MiRTLE system is approved for sale in European countries that accept CE mark certification. The system is not yet approved for sale in the US.

There are no minimum order or quantities to be sold, and Imricor will not hold inventory of MiRTLE systems. For each system sold, Imricor will pay MiRTLE a fixed price.

The Agreement represents a significant step for Imricor given the need for Imricor to provide an MRI-compatible 12-lead ECG system to customers for ventricular tachycardia ablations. The Company has previously announced its strategy to expand indications in Europe to ventricular tachycardia, with a pre-clinical trial study scheduled for the fourth quarter of 2021, a European clinical trial expected to commence in 2022, and CE mark approval expected at the end of 2023. The revenue from selling the MiRTLE system is not expected to be material relative to revenue from the Company's own products.

#### **IDE Submission to FDA Delayed**

The Company previously disclosed its intent to submit for an Investigational Device Exception (IDE) to the US Food and Drug Administration (FDA) by the end of September 2021. Once approved, the IDE will enable Imricor to initiate and conduct a clinical trial to support FDA approval, opening the US market for Imricor's products. The IDE approval process typically takes approximately 90 days.



A delay in documentation from Imricor's partner, Osypka AG Medizintechnik (Osypka), has resulted in a delay to the IDE submission. Once the documentation is received from Osypka, it will be integrated into the submission package and submitted to the FDA.

The Company does not believe the delay in receiving the documentation will result in a material delay in FDA approval, which is still targeted for the end of 2023.

### **European Cardiology Congress Participation**

The Company previously disclosed its intent to participate in country-specific cardiology congresses throughout Europe with the goal of increasing awareness of Imricor's products and solutions through face-to-face engagement with physicians.

To that end, the Company participated in the Italian Association of Arrhythmology and Cardiac Stimulation (AIAC) Congress, held in Bologna, Italy on 16-17 September 2021.

In addition, Imricor is slated to participate in the German Cardiology Society's (DGK) Heart Days in Bonn, Germany on 30 September – 2 October 2021.

Imricor will also be participating in the Netherlands Heart Rhythm Association (NHRA) Annual Congress in Amstelveen, the Netherlands, on 3 November 2021.

Additional congresses will be added to the schedule in 2022.

### **ENDS**

Authorised for release by Steve Wedan, Executive Chair, President, and CEO.



## **Further Information**

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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.