



## VISABL-AFL TRIAL FOR US FDA APPROVAL COMMENCES AT CARDIOVASCULAR INSTITUTE OF SOUTH PARIS

### Highlights:

- Two VISABL-AFL procedures were performed today at the Cardiovascular Institute of South Paris (ICPS)
- NorthStar 3D Mapping system called a “game-changer” for the field
- VISABL-AFL is the global clinical trial supporting US FDA approval
- Full trial enrolment on track to be completed in 2024

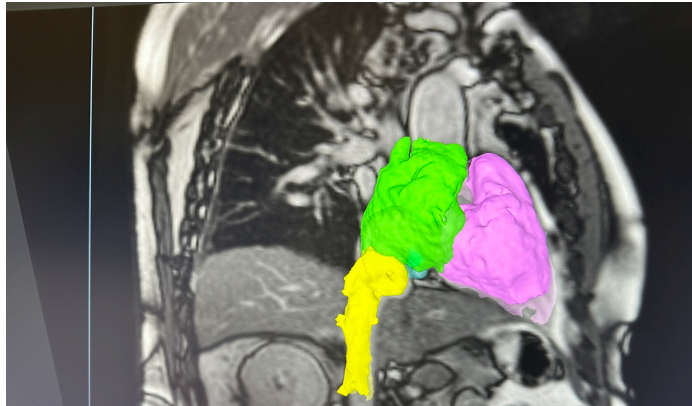
**21 June 2024** – Melbourne, Australia (**20 June 2024** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)** is pleased to announce that VISABL-AFL, the global clinical trial supporting US Food and Drug Administration (FDA) approval, commenced with two procedures performed today at the Cardiovascular Institute of South Paris (ICPS) (<https://icps.fr>).



“We did the first two cases of RF flutter ablation with the Imricor system, and it went quite smoothly. We are very enthusiastic about it!”

- **Professor Jerome Garot**  
**Head of Cardiovascular Magnetic Resonance**

**Dr Laurent Fiorina, the operating Electrophysiologist at ICPS and the site’s Principal Investigator commented:** “Enrolling the first patients in the VISABL-AFL clinical trial represents a significant step forward for the future of 3D real-time MRI ablations in the iCMR lab. Performing procedures with Imricor’s NorthStar 3D Mapping System is a game-changer for this field, and it will have a transformative impact. I look forward to the continued partnership with Imricor.”



**Imricor's NorthStar 3D Mapping System being used in VISABL-AFL procedure**

The VISABL-AFL (“**V**ision-**M**R **A**blation of **A**trial **F**lutter”) clinical trial, (ClinicalTrials.gov Identifier: NCT0504548) is a prospective, single-arm, multi-centre global investigational study of the safety and efficacy of type I atrial flutter ablation procedures performed with the Vision-MR Ablation Catheter (second generation) and Osypka HAT 500 RF generator and irrigation pump.



**VISABL-AFL procedure at ICPS**

The study will include four sites across the United States and Europe. The sample size is 91 patients, with an interim analysis after 76 patients have achieved the 7-day follow-up. The Company expects to complete trial enrolment before the end of the year.

**Imricor's Chair and CEO, Steve Wedan, commented:** “This is a huge milestone for all of us at Imricor. Special thanks to Kate Lindborg, our Senior Director of Clinical Affairs, and her entire team. We are on track with VISABL-AFL to complete enrolment this year, supporting our goal of FDA approval for our platform of technology in the US in 2025.”

**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 and the Kingdom of Saudi Arabia (KSA) 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 Australia, 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 CHES Depository 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.