IMRICOR TO COMMENCE VISABL-AFL CLINICAL TRIAL AT JOHNS HOPKINS HOSPITAL

Highlights:

- **Johns Hopkins Hospital's Institutional Review Board (IRB) has approved commencement of the VISABL-AFL clinical trial**
- **Enrolment is expected to begin within the next month**
- **VISABL-AFL is the clinical trial to support FDA approval in the US**

17 January 2024 – Minneapolis, MN United States (**18 January 2023** – Melbourne, Australia) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) is pleased to announce that the VISABL-AFL clinical trial has been approved by Johns Hopkins Hospital's Institutional Review Board (**IRB**). First enrolment is expected within the next few weeks.

VISABL-AFL is the clinical trial supporting US FDA approval of Imricor's products.

Imricor's Chair and CEO, Steve Wedan, commented: "This is a major milestone in our FDA approval process, and we are privileged to be able to commence our VISABL-AFL trial at the globally-renown Johns Hopkins Hospital.

"As a company, we are pleased that the work that we have quietly gone about over the past 12-18 months is enabling us to start the year with strong momentum. Last week, we secured Saudi FDA approval, and now we have Johns Hopkins IRB approval. Things are coming into place nicely, and we have many more great milestones ahead of us."

VISABL-AFL 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 HAT 500 RF generator and irrigation pump.

The study will include sites in the US and Europe. The sample size is 91 patients, with an interim analysis after 76 patients have achieved the 7-day follow-up.

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 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 Middle East.

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.