IMRICOR SUCCESFULLY COMPLETES HUMAN FACTORS STUDY FOR ALL DEVICES IN FDA APPROVAL PATHWAY

18 September 2025 – Melbourne, Australia (**17 September 2025** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**), is pleased to announce the successful completion of its Human Factors (HF) study covering all of the Company's devices currently under review by the U.S. Food and Drug Administration (FDA).

Background

The HF study is a critical step in the FDA approval process, ensuring that each device can be used safely and effectively by clinicians in real-world settings. Completion of this extensive study across Imricor's full product portfolio represents a major milestone in advancing toward FDA market approval.

This achievement highlights both the scale and complexity of the project, which required comprehensive testing across multiple devices, workflows, and clinical scenarios. Importantly, it also underscores the strong momentum Imricor is building as the Company continues to progress through the U.S. regulatory pathway.

With the HF study now complete, Imricor is one step closer to unlocking access to the world's largest electrophysiology market, representing a significant growth opportunity for the Company and a major inflection point in its global strategy.

Highlights

- A 7-month usability study involving 46 healthcare professionals, comprising 23 electrophysiologists and 23 EP nurses/technologists from hospitals across the U.S.
- Physicians from close to 20 U.S. hospitals participated in the study
- Evaluation and successful completion of safety and usability testing for nine separate Imricor products, whereas most companies typically test only one or two devices
- Comprehensive risk documentation review, improvements and finalisation of Instructions for Use (IFUs) is now complete

Imricor's Chair and CEO, Steve Wedan, commented: "The scale of this study cannot be overstated, having taken our team over a year from planning through execution. Completing human factors testing across our entire product portfolio is an extraordinary achievement and a clear demonstration of the strength and dedication of the Imricor team. It also marks a major milestone on our path to FDA approval and positions us strongly as we prepare to bring MRI-guided ablation to the United States.

"I am grateful to the physicians and medical staff that took the time to travel to the Imricor's iCMR Design Centre in Minneapolis to complete this study. They have played an important and vital role in shaping the future of Imricor and of interventional medicine."

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 striving to make interventional medical procedures better, safer, and more cost effective by making it possible for these procedures to be performed under real-time magnetic resonance imaging (MRI) guidance, rather than under x-ray fluoroscopy guidance, thus taking advantage of MRI's superior imaging capabilities.

Imricor's Products

Imricor is a pioneer and leader in developing MRI-compatible products for cardiac catheter ablation procedures, and 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 for the sale of its NorthStar 3D Mapping System, the Advantage-MR EP Recorder/Stimulator System and other consumable products, such as the Vision-MR Diagnostic Catheter 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.