FDA CLEARS VISION-MR DIAGNOSTIC CATHETER

12 January 2026 – Melbourne, Australia (**11 January 2026** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) is pleased to announce that the United States Food and Drug Administration (FDA) has granted 510(k) clearance for the Company's **Vision-MR® Diagnostic Catheter** under the premarket notification process.

This marks the Company's first FDA clearance.

The Vision-MR Diagnostic catheter is designed to be used under real-time magnetic resonance imaging (MRI) guidance and represents a key component of Imricor's comprehensive platform of MRI-compatible electrophysiology (EP) devices.

FDA clearance enables Imricor to commercially market the Vision-MR Diagnostic Catheter in the United States, the world's largest electrophysiology market. This clearance is the first of what the Company expects will be multiple regulatory clearances and approvals this calendar year, as Imricor's full MRI guided EP platform is progressively introduced to the market.

Imricor's Chair and CEO, Steve Wedan, added: "This is obviously a tremendous milestone for the Imricor team, and I want to acknowledge the outstanding work of the entire team in reaching this achievement. Most of us have worked at companies that have existing medical devices on the US market, and getting a new device on the market is always a big deal. But getting a company's *first* device on the US market is an extraordinarily big deal. It's an exciting achievement and a date to be noted and remembered."

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

Media and Investor Relations Contacts:

Simon Hinsley
Executive Director, NWR
simon@nwrcommunications.com.au
+61 401 909 653

Nick Corkill
VP Corporate Strategy, Imricor
nick.corkill@imricor.com
+61 450 475 633

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 world leader in developing MRI-compatible products for cardiac catheter ablation procedures. The Company's products include capital equipment, such as the NorthStar® Mapping System and the Advantage-MR® EP Recorder/Stimulator. Single-use devices include a variety of ablation catheters, diagnostic catheters, steerable sheaths, and other tools used for cardiac ablations.

Imricor's products are approved in the European Union, the Kingdom of Saudi Arabia, and New Zealand. US FDA approval is in process, and further approvals in other geographies such as Australia are being planned.

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.