IMRICOR SUBMITS 3RD MODULE OF PMA APPLICATION TO FDA FOR INTERVENTIONAL MR CARDIAC ABLATION TECHNOLOGY

Highlights

- **Imricor has submitted Module 3, of its four-module Premarket Approval (PMA) application to the U.S. Food and Drug Administration (FDA)**
- **Module 3 comprises non-clinical bench testing results**
- **Devices included in the submission are the Vision-MR Ablation Catheter 2.0, RF-5000 Ablation Generator, and RF-5000 Irrigation Tubing Set**
- **The remaining Module 4 is the clinical module, comprising data from the Company's VISABL-AFL trial which is in the later stages of completion**
- **The PMA seeks US approval of Imricor's therapy delivery devices, led by the Vision-MR Ablation Catheter 2.0, for the treatment of type I atrial flutter under real-time interventional Magnetic Resonance (iMR) guidance**

11 June 2026 – Melbourne, Australia (**10 June 2026** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) is pleased to announce that it has submitted the third Premarket Approval (PMA) module for U.S. Food and Drug Administration (FDA) review.

The third module covers non-clinical bench testing, which includes the design, execution, and results of all non-clinical (so-called "bench") tests associated with the Vision-MR Ablation Catheter 2.0, RF-5000 Ablation Generator, and RF-5000 Irrigation Tubing Set. These bench tests include product performance, sterile shelf life, packaging integrity, software testing, electrical safety, electromagnetic compatibility, magnetic resonance safety, and usability.

Imricor is executing a modular review process with the FDA, whereby modules covering various aspects of the Company's products are submitted and reviewed serially, with the goal of achieving a more streamlined review process. Concurrently, the team are pursuing multiple FDA clearances for their portfolio devices which follow the 510(k) pathway. So far, three products have received 510(k) clearance: NorthStar, Vision-MR Diagnostic Catheter, and Vision-MR Diagnostic Catheter Cable.

Imricor's Chair and CEO, Steve Wedan, commented: "This is another significant regulatory milestone for Imricor. The submission, which exceeds ten thousand pages, represents years of design, manufacturing, and testing of the most sophisticated interventional MR tools in existence. It is a tremendous effort that spans not only our Regulatory group, but also our Design Assurance, Quality, R&D, and Operations groups. These teams continue to keep us on track for FDA approval and clearance of our platform products in the US this year."

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 (MR) guidance, rather than under x-ray fluoroscopy guidance, thus taking advantage of MR's superior imaging capabilities.

Imricor's Products

Imricor is a pioneer and world leader in developing MR-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. NorthStar is approved in the US.

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 excluding qualified institutional buyers (QIBs, as defined in Rule 144A under the Securities Act). 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.