



FDA COMPLETES REVIEW OF THIRD PMA MODULE

Key Highlights

- **Module 3 is the largest PMA module and covers non-clinical bench testing associated with the Vision-MR Ablation Catheter 2.0, RF-5000 System (Generator, Pump, Remote), and RF-5000 Irrigation Tubing Set**
- **No deficiencies identified for the Vision-MR Ablation Catheter 2.0**
- **No deficiencies identified for the RF-5000 Irrigation Tubing Set**
- **One deficiency identified for the RF-5000 System**
- **The single deficiency relates to the ablation generator's third-party software operating system, which the Company has already updated**
- **Response to the FDA is underway, and upon acceptance, Module 3 will be closed**
- **Module 4 submission is targeted for November, completing all submissions**

08 October 2026 – Melbourne, Australia (**07 October 2026** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)** is pleased to announce that it has received notice from the U.S. Food and Drug Administration (FDA) that the FDA has completed its review of the Company's third Premarket Approval (PMA) module. The third module contains the design, execution, and results of all non-clinical (so-called "bench") tests associated with the Vision-MR Ablation Catheter 2.0, RF-5000 System (comprising the ablation generator, irrigation pump, and remote unit), 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.

The FDA identified one deficiency, which requires a response from the Company prior to acceptance and closure of the module. The deficiency was that the software operating system in the RF-5000 system was no longer under Long-Term Support from its manufacturer. The Company has already updated the operating system to a version that is under Long-Term Support, and the Company is preparing its response to the FDA.

Module 3 was submitted to the FDA on 11 June 2026.

Imricor's Chair and CEO, Steve Wedan, commented: "Module 3 is the largest and most technically detailed part of our PMA. It covers every bench test across the ablation catheter, generator, pump and irrigation tubing set, from product performance and shelf life through to software, cybersecurity, electrical safety and MR safety. To complete an FDA review of that scope with a single deficiency, and one we have already addressed, is a credit to the rigor our engineering and regulatory teams have applied throughout this program. With the manufacturing module already closed, we continue to work methodically through each component of the PMA as we advance toward delivering a complete, radiation-free iMR ablation platform to U.S. physicians and patients."



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 interventional MR (iMR) 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 in an iMR lab.

Imricor's products are approved in the European Union, the Kingdom of Saudi Arabia, and New Zealand. NorthStar and Vision-MR Diagnostic Catheter are cleared 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.