FDA ACCEPTS IMRICOR'S PMA MANUFACTURING MODULE

Key Highlights

- **The U.S. Food and Drug Administration (FDA) has notified Imricor that it has completed its evaluation of the manufacturing module of the Company's Premarket Approval (PMA) submission**
- **The manufacturing module has been accepted by the FDA and is considered closed**
- **The module covers the design, manufacturing and quality processes surrounding seven products, including the Vision-MR® Ablation Catheter and the RF-5000™ Ablation Generator and Pump**
- **Closure of the manufacturing module is a major milestone in the Company's modular PMA review with the FDA**
- **An FDA pre-approval inspection of the Company's manufacturing sites will be conducted prior to any final PMA approval**

03 September 2026 – Melbourne, Australia (**02 September 2026** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc.** (**Company** or **Imricor**) (**ASX: IMR**) is pleased to announce that it has received notification from the U.S. Food and Drug Administration (**FDA**) that the FDA has completed its evaluation of the manufacturing module of the Company's Premarket Approval (**PMA**) submission, and that the module has been accepted and is considered closed.

The manufacturing module covers the design, manufacturing and quality processes surrounding seven products in total. Six of these are the Company's own products undergoing the FDA's PMA process, including the Vision-MR® Ablation Catheter and the RF-5000™ Ablation Generator and Pump, together with a third-party product that Imricor will distribute. The module encompassed design controls, the receipt, inspection and storage of raw materials, build procedures, process validation, part and device traceability, and the applicable quality management systems. Given the number of devices involved, it was one of the largest and most complex components of the Company's PMA submission.

Imricor is executing a modular review process with the FDA, in which modules covering different aspects of the Company's products are submitted and reviewed serially. Under this process, once

the FDA accepts and closes a module, that module **is not expected to be re-reviewed** as part of the final PMA review unless changes are subsequently made to its contents. With the manufacturing module now closed, Imricor has achieved another major milestone toward FDA approval of the products engaged in the PMA process.

Prior to any final PMA approval, the FDA will also conduct a pre-approval inspection of the Company's manufacturing sites. Final approval remains subject to the FDA's satisfactory completion of its review of all modules and the pre-approval inspection.

Imricor's Chair and CEO, Steve Wedan, commented: "Manufacturing is one of the most demanding components of any PMA, and ours covered seven devices at once. To have the FDA complete its evaluation and close this module is a strong validation of the design controls, production processes and quality system our team has built. It is the kind of milestone that is easy to state in a sentence but very hard to earn.

"We continue to progress through multiple FDA processes – both 510(k) and PMA – across a broad portfolio of electrophysiology devices to support the commercial launch of our EP platform in the United States. Every closed module brings us a step closer to delivering iMR-guided EP to U.S. physicians and their 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.