



## IMRICOR RECEIVES APPROVAL FROM SAUDI FOOD AND DRUG AUTHORITY

### Highlights:

- Imricor has obtained Medical Device Marketing Authorization from the Saudi Food & Drug Authority and is now launching commercialization efforts in the Kingdom of Saudi Arabia
- The first system sale is expected in KSA within six months
- KSA market performs nearly 50,000 cardiac ablation procedures annually
- KSA is a significant market for Imricor, especially in light of the Saudi Vision 2030 Health Sector Transformation Program
- Strategically significant approval for Imricor marking Middle East as the 2<sup>nd</sup> region now in commercialisation

**10 January 2024 – Minneapolis, United States (11 January 2024 – Melbourne, Australia) – Imricor Medical Systems, Inc. (Company or Imricor) (ASX:IMR)** the global leader in real-time iCMR cardiac ablation products, is pleased to announce it has received Medical Device Marketing Authorization (**MDMA**) from the Saudi Food & Drug Authority (**SFDA**).

MDMA clears the way for Imricor to begin commercialisation efforts in the Kingdom of Saudi Arabia (**KSA**) through, and in cooperation with, Imricor's exclusive distributor, Al Faisaliah Medical Systems (**FMS**). FMS a prominent distributor in KSA, with an impressive track record of success and more than a billion dollars in annual revenue. FMS brings a wealth of expertise and a robust distribution network to ensure seamless market penetration for Imricor's technology in KSA.

Nearly 50,000 cardiac ablation procedures are performed annually in KSA, and that number is expected to grow as part of Saudi Vision 2030's Health Sector Transformation Program (<https://www.vision2030.gov.sa/en/vision-2030/vrp/health-sector-transformation-program/>).

This milestone underscores Imricor's progress and commitment to expansion and continued growth in strategic markets.

**Imricor's Chair and CEO, Steve Wedan, said:** "We are extremely pleased to receive SFDA approval, and the timing is great, with the Arab Health Medical Expo commencing in less than three weeks. We are very excited to launch our products and grow our business across KSA. This is another significant milestone in pursuit our vision to deliver real-time iCMR ablations to patients and physicians worldwide."

**FMS, Subsidiary of Tibbiyah Holding Company CEO, Alaa Ameen, said:** "With our partnership with Imricor, we're extremely excited in bringing the unique Imricor iCMR technology to Saudi cardiac Centres that aim to be worldwide leaders in patient outcomes. I'm confident that this state-of-the-art technology will add value to patient outcomes and meet the expectations of the Saudi cardiac Centres. In Tibbiyah Holding Company, we are doing our best to align our customers' goals with Saudi Vision 2030 to establish the best cardiac Centres in the Middle east region."

**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 a leading developer of innovative MRI-compatible medical devices which can be used to carry out real-time iCMR cardiac ablation procedures. Headquartered in the US, Imricor seeks to make a meaningful impact on patients, healthcare professionals, and healthcare facilities around the world by increasing the success rates and bringing down the overall costs of cardiac ablation procedures.

### Imricor's Products

Imricor is a pioneer and leader in developing MRI-compatible products for cardiac catheter ablation procedures, and believes 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 with an indication for treating type 1 atrial flutter. Imricor intends to seek approval for expanded indications in the future. The Company is also in the early stages of pursuing the required regulatory approvals to place its key products on the market in Australia and the U.S.

The Company has also obtained approval within the EU for the sale of the Advantage-MR EP Recorder/Stimulator System and its consumable product, the 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. and Siemens Healthcare GmbH help to target certain sites and support the design and construction of iCMR labs for those sites.

### 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.

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