



IMRICOR BUSINESS UPDATE

Highlights:

- Imricor's NorthStar 3D mapping system added to the VISABL-VT study protocol and submitted for approval to commence the study at Haga Hospital in the Netherlands
- VISABL-VT study subsequently received the Netherlands CCMO (Central Committee on Research Involving Human Subjects) approval
- The last approval required to commence the study is a review by Haga Hospital's Ethics Committee which is scheduled to take place on May 2nd
- Steps are underway to adapt Imricor's NorthStar 3D mapping system to Philips and GE HealthCare MRI platforms
- Commercial relaunch gaining momentum with twice as many procedures performed in Q1 2023 compared to Q4 2024

12 April 2023 – Minneapolis, MN United States (**13 April 2023** – Melbourne, Australia) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)** is pleased to provide the following business update.

VISABL-VT Clinical Trial Approval Process

The Company recently completed the design, testing, and documentation of Imricor's NorthStar 3D mapping system, which allowed the Company to add NorthStar to the VISABL-VT study protocol and submit for approval to commence the study at Haga Hospital in The Hague, Netherlands. NorthStar is required for the VISABL-VT trial at Haga Hospital because the iCMR lab there is based on the Siemens MRI platform, and NorthStar is the only 3D mapping system that operates with Siemens MRI systems.

Today, Imricor received notice from the Netherlands *Central Committee on Research Involving Human Subjects* (CCMO) that their review is complete, with positive results, meaning that the last step in the study approval process for the Netherlands is a review by Haga Hospital's Ethics Committee. The Company additionally received notice that the Haga Hospital Ethics Committee will review the study on May 2nd. Upon approval by Haga Hospital's Ethics Committee, the VISABL-VT trial can commence at that site.

Imricor's Chair and CEO, Steve Wedan, commented: *"The Imricor team has worked with great efficiency and diligence to complete NorthStar's development and to add it to the VISABL-VT study protocol, such that iCMR sites with Siemens MRI systems can participate in the trial. As we expected, the study approval process in the Netherlands is moving more quickly than the process in Germany."*

"Recall that we submitted for approval to commence VISABL-VT at the Leipzig Heart Centre in Germany last September. We were able to apply earlier, there, because the Leipzig Heart Centre's iCMR lab is based around the Philips MRI platform which currently utilises Philips' existing iSuite mapping system. Our urgency around NorthStar's completion was driven by our



desire to expand the VISABL-VT study to include sites, like Haga Hospital, that have Siemens iCMR labs and to expand the study to other countries.

“We look forward to commencing the VISABL-VT trial and bringing the benefits of real-time iCMR ablations to patients suffering from ventricular tachycardia, a very serious and complex arrhythmia.

“Once again, I want to underscore the value and significance of our NorthStar mapping system, which has provided us with much more control and influence over our timelines. Ultimately, we expect that NorthStar will be the 3D mapping system used on other MRI platforms as well, including those from Philips and GE HealthCare.”

The VISABL-VT trial is a prospective, single-arm, multi-centre investigation of the safety and efficacy of radiofrequency (RF) ablation of ventricular tachycardia (VT) associated with ischemic cardiomyopathy performed with the Vision-MR Ablation Catheter 2.0 in the iCMR environment. The study calls for treating 64 patients and includes a 6-month follow-up for each patient. The study is intended to support CE mark certification of the Vision-MR Ablation Catheter 2.0 for treating VT.

NorthStar’s Expansion to Other MRI Platforms

Imricor is participating, this week, in a multi-day in-person meeting of the *Sensing and Image-Guided Neurological therapies, cardiac Electrophysiology and Tumour treatments* (SIGNET) consortium at the Amsterdam University Medical Centre in the Netherlands. An overview of SIGNET can be found here: <https://itea4.org/project/signet.html>.

Imricor’s SIGNET involvement is the mechanism through which the Company and Philips will collaborate to develop the software necessary for Imricor’s NorthStar 3D mapping system to operate with the Philips MRI platform.

Imricor’s Chair and CEO, Steve Wedan, commented: *“SIGNET provides a way for us to ultimately bring NorthStar to our customers utilising MRI systems from Philips. This brings us one step closer to fulfilling our goal for NorthStar to be the central component of any iCMR program, and the 3D mapping system used for interventions performed in every iCMR lab, no matter what MRI platform is present.”*

The Company further expects to sign a Master Services Agreement with GE HealthCare in the coming days, which will open the door for Imricor to begin the development of the software necessary for NorthStar to operate with the GE HealthCare MRI platform.

Q1 Procedure Volume

Ahead of the Q1 Appendix 4C cash flow release later this month, the Company announces today that twice as many procedures were performed in Q1 2023 compared to Q4 2024. Twenty-eight procedures were performed in Q1, making it the highest volume quarter in the Company’s history.

Imricor’s Chair and CEO, Steve Wedan, noted: *“Whilst the issues of MRI availability at sites where the MRI is a shared resource between departments continues to be an issue, and whilst we continue (for now) to find fewer patients presenting to their doctors with standalone atrial flutter compared to pre-pandemic times, we are nonetheless seeing an uptick in procedures volumes,*



and we hope to continue the trend as more sites become active and engaged. Notably, the Amsterdam University Medical Centre performed three iCMR ablation procedures in one day last week.

"We are still in the early stages of our commercial relaunch following the pandemic, and we will continue to focus on developing an installed base of cardiology-owned iCMR labs to drive consistent and sustained growth into the future. The upcoming availability of NorthStar and the anticipation around the VISABL-VT trial is helping to generate renewed excitement in the field, and we are beginning to regain the momentum we had in early 2020."

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.