

## **BUSINESS UPDATE**

**22 October 2019 – Minneapolis, United States – Imricor Medical Systems, Inc. (Company or Imricor) (ASX:IMR)** today provides the following business update.

### **CE Mark and Lab Rollout**

Consistent with the previous update on 26 September, Imricor advises that while the CE mark remains outstanding, the certification process for the Vision-MR Ablation Catheter continues to progress, no issues or concerns about the safety and performance of the catheter have been identified by the Company's Notified Body, TÜV SÜD, and the Company continues to engage regularly with TÜV SÜD. While Imricor continues to believe that the review process will be finalised shortly, the exact date of receipt of the CE mark remains uncertain.

Imricor had given previous guidance that the Company aimed to have 13 iCMR lab sites purchasing consumable products by the end of 2019. This timetable assumed that the Company would undertake a controlled limited release of its approved products within the three months following receipt of the CE mark. As a consequence, the Company now expects that a number of lab sites will commence purchasing consumable products during the first quarter of 2020, rather than the fourth quarter of 2019. The actual number that will be delayed will depend on the date on which CE Mark approval is received.

Despite the delay, and consistent with previous guidance, the Company believes that the pipeline for lab adoption is progressing well and the Company continues to identify additional hospitals interested in early adoption of MR-guided atrial flutter ablations.

### **Financial Forecast**

There will be an impact on the financial forecast, due to the delay in commencement of capital and corresponding consumable sales. Separately, the Company was scheduled to earn license revenue totaling \$1.25m in 2019 based on milestones achieved in collaboration with the licensee. The Company and licensee are currently evaluating certain changes to the prototype design. As a result, these milestones are now expected to be achieved, and the corresponding revenue earned, in 2020. The Company will address the aggregate impact on its financial forecast once it has further clarity on timing of its CE mark.

Commenting on the current status of the process, Imricor Chair and CEO, Mr Steve Wedan, said "While we are disappointed with this CE mark delay, we remain encouraged by our engagement with TÜV SÜD and with lab sites. We also remain confident that the initial rollout program can be completed within the previously indicated timeframe of three months following receipt of CE mark. Similarly, we continue to work collaboratively with our licensee and believe we will receive the license revenue. I do not believe the delay in the CE mark process and the license payments impact the long-term prospects of the Company; the fundamentals of Imricor are unchanged. We are executing the same plan in the same market with the same demand and the same value proposition."

The Company will host a conference call during the coming week in conjunction with the release of its September quarter Appendix 4C cash flow report. Details to follow.

**ENDS**



## **Further Information**

### **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 MRI-guided cardiac catheter 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 catheter ablation procedures.

## **Foreign Ownership Restrictions**

Imricor's CHES 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. 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.