

First implant in the Totally Leadless CRT (TLC-AU) Study

Key Highlights

- First patient enrolment and implant in the Totally Leadless CRT (TLC-AU) study by Dr Paul Gould from the Princess Alexandra Hospital, Brisbane
- TLC-AU is a feasibility study into using the WiSE® System alongside a leadless pacemaker to achieve totally leadless CRT
- The study represents a significant strategic milestone as EBR evaluates WiSE as a potential first-line therapy for treating newly diagnosed heart failure patients
- TLC-AU could meaningfully expand EBR's addressable market

Sunnyvale, California; 12 December 2025: EBR Systems, Inc., developer of the world's only wireless cardiac pacing device for heart failure, announces the first enrolment and implant of the WiSE System into a patient in the Totally Leadless CRT (TLC-AU) study.

The procedure, performed on Thursday 11 December (Australian time), was undertaken at the Princess Alexandra Hospital in Brisbane, Australia, by respected electrophysiologist Dr Paul Gould. The WiSE System was implanted alongside an Abbott Aveir™ DR leadless pacemaker.

Totally Leadless CRT, pairing EBR's WiSE System with a leadless right ventricle pacemaker, has been previously published¹, and is already included in the FDA-approved labelling for patients with an existing leadless pacemaker who subsequently develop pacing-induced heart failure and require an upgrade to CRT.

The TLC-AU study will build on this previous published experience by treating newly diagnosed heart failure patients requiring CRT. These de novo patients will receive a leadless pacemaker and the WiSE System. De novo patients account for around 75% of the CRT market, meaning this indication has the potential to significantly expand EBR's total addressable market and establishing WiSE as a potential first-line option for patients requiring CRT.

John McCutcheon, President & CEO of EBR Systems, said: *"The first implant in the TLC-AU Study is a significant milestone for EBR, marking our entry into the much larger frontline CRT market. TLC-AU allows us to build on the FDA-labelled upgrade indication and generate the evidence needed to position WiSE CRT as a fully leadless alternative for patients requiring resynchronisation therapy. As leadless pacing rapidly becomes standard of care, advancing a totally leadless CRT solution strengthens EBR's leadership in the next major evolution of heart-failure treatment."*

Dr Paul Gould, MBBS, FRACP, FCANZ, Principal Investigator for the study said: *"It was a privilege to lead the team completing the first Totally Leadless CRT implant in this feasibility study. The team at Princess Alexandra Hospital was proud to contribute to this important milestone and to support the evaluation of a totally leadless cardiac resynchronisation option for heart failure patients. We believe this study will provide valuable insights into the role that Totally Leadless CRT may play in expanding treatment options for suitable patients in the future."*

About the study

The study, which is being sponsored by EBR Systems, is a single-arm, prospective, multi-centre feasibility study.

¹ Source: <https://academic.oup.com/europace/article/23/5/740/6032815?login=false>

It will enrol 20 to 40 patients across up to five Australian centres, including both patients receiving CRT for the first time and patients being upgraded from an existing intracardiac pacemaker. The study will follow patients for 6 months.

The primary objective is to assess the safety and efficacy of the co-implantation of the WiSE CRT System with an intracardiac pacemaker to provide totally leadless CRT. The secondary objective is to assess clinical response to totally leadless CRT provided by the co-implantation of the WiSE CRT System with an intracardiac pacemaker at six months compared to baseline.

ENDS

This announcement has been authorised for release by the Routine Disclosure Committee, a Committee of the Board.

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About EBR Systems

Silicon Valley-based EBR Systems (ASX:EBR) is dedicated to superior treatment of cardiac rhythm disease by providing more physiologically effective stimulation through wireless cardiac pacing. The patented proprietary Wireless Stimulation Endocardially (WiSE) technology was developed to eliminate the need for cardiac pacing leads, historically the major source of complications, effectiveness and reliability issues in cardiac rhythm disease management. The initial product is designed to eliminate the need for coronary sinus leads to stimulate the left ventricle in heart failure patients requiring Cardiac Resynchronisation Therapy (CRT). Future products potentially address wireless endocardial stimulation for bradycardia and other non-cardiac indications.

EBR Systems' WiSE Technology

EBR Systems' WiSE technology is the world's only wireless, endocardial (inside the heart) pacing system in clinical use for stimulating the heart's left ventricle. This has long been a goal of cardiac pacing companies since internal stimulation of the left ventricle is thought to be a potentially superior, more anatomically correct pacing location. WiSE technology enables cardiac pacing of the left ventricle with a novel cardiac implant that is roughly the size of a large grain of rice. The need for a pacing wire on the outside of the heart's left ventricle – and the attendant problems – are potentially eliminated. WiSE is an investigational device in most markets and is currently only available for sale in the US.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties, contingencies and other factors, many of which are beyond the Company's control, subject to change without notice and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products and achieve broad market adoption including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products; our expectations with respect to our clinical trials, including enrollment in or completion of our clinical trials and our associated regulatory applications and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position. These forward-looking statements are based on EBR Systems' current expectations and inherently involve significant risks and uncertainties. EBR Systems' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of certain risks and uncertainties including those risks described in more detail in its most recently filed Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and other documents on file with the SEC from time to time and available on the SEC's website at www.sec.gov.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. EBR 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. EBR may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

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