

EBR Receives Preliminary Approval for Transitional Pass-Through (TPT) Reimbursement

Key highlights:

- The U.S Centers for Medicare & Medicaid Services' (CMS) has granted preliminary approval for EBR's WiSE® CRT System for the Transitional Pass-Through (TPT) reimbursement scheme
- TPT reimbursement will drive increased hospital adoption and provide a clear reimbursement pathway for EBR's WiSE CRT System in an outpatient setting
- TPT reimbursement is expected to commence during October 2025 and will be effective for 3 years
- EBR will continue to engage with CMS as the process moves through final rulemaking and public comment
- CMS previously proposed approval of the New Technology Add-On Payment (NTAP) reimbursement for inpatients

Sunnyvale, California; 15 July 2025: EBR Systems, Inc. (ASX: "EBR", "EBR Systems", or the "Company"), developer of the world's only wireless cardiac pacing device for heart failure, is pleased to announce that the U.S. Centers for Medicare & Medicaid Services (CMS) has provided preliminary approval for the Transitional Pass-Through (TPT) reimbursement scheme for EBR's WiSE® CRT System. Preliminary approval, which is expected to become effective October 2025, will provide hospitals with Medicare reimbursement when treating patients in an outpatient setting with the WiSE CRT System for a period of three years.

The TPT reimbursement program is designed to facilitate hospital adoption of breakthrough medical technologies that demonstrate substantial clinical improvement for patients, but whose costs are not yet fully incorporated in standard Medicare payment rates. Preliminary approval is a significant commercial milestone, as access to the TPT reimbursement scheme will support hospital adoption for outpatients and allow EBR's commercial team to present a clear reimbursement pathway to hospitals.

Following preliminary approval, EBR will continue to engage with CMS through the upcoming annual rulemaking and public comment process, with a final determination to follow.

John McCutcheon, EBR Systems' President & Chief Executive Officer said:

"We are excited to receive preliminary approval of TPT reimbursement for EBR's WiSE System. This major milestone along with CMS's previous proposal to approve NTAP reimbursement will allow us to target broad patient access for WiSE in the US. Both these outpatient and inpatient reimbursement schemes are expected to become effective from October 2025. We look forward to continuing our engagement with the CMS to accelerate widespread adoption of WiSE."

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 including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment 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.

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.

Foreign Ownership Restriction

EBR'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 or sales 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. The holders of EBR's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.