ASX ANNOUNCEMENT **20 January 2025**

WiSE accepted into the CMS' newly enacted TCET reimbursement pathway

Key highlights

- EBR's WiSE System has been accepted into the Centers for Medicare & Medicaid Services' (CMS) new and highly selective Transitional Coverage for Emerging Technologies (TCET) reimbursement pathway
- The TCET pathway is designed for select FDA-designated Breakthrough Devices and facilitates an expedited Medicare explicit coverage for those devices deemed particularly impactful
- CMS has initiated an Evidence Preview to assess potential benefits, harms and evidence, enabling early engagement with the CMS and underpinning an efficient review process

Sunnyvale, California; 20 January 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 CMS has accepted EBR's WiSE System (WiSE) into the TCET pathway and that the U.S. Food and Drug Administration (FDA) has completed the manufacturing Pre-Approval Inspection (PAI) of EBR's facilities, with no observations made.

WiSE accepted into the Transitional Coverage for Emerging Technologies pathway

CMS has accepted EBR's WiSE® System into the TCET pathway. This program is designed to expedite Medicare coverage for a highly selective subset of FDA-designated Breakthrough Devices. This allows patients early access to especially important innovative medical technologies. Acceptance into the TCET pathway provides several key benefits for EBR Systems, including:

- **Early CMS engagement:** Collaborating early with the CMS supports an efficient review process and aligns evidence generation with regulatory and Medicare expectations
- **Expedited Medicare coverage:** Enables Medicare coverage for the WiSE system, including transitional coverage of up to five years
- **Selective acceptance into the program:** CMS has Indicated that they expect to only accept five new technologies each year into the pathway

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

"EBR is honoured that WiSE is one of the first five technologies that CMS indicated will be approved to participate in the inaugural year of the CMS TCET pathway. This is a new program that provides a faster path to a national coverage decision for medical devices that have the FDA breakthrough device designation status. This program runs parallel with the New Technology Add-on Payment and Transitional Pass-Through Payment programs for new devices with breakthrough status. We will provide further updates as we make progress through this exciting, new program."

ENDS

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

For more information, please contact:

Company
Gary Doherty
Chief Financial Officer
P: +1 408 720 1906
E: info@ebrsystemsinc.com

Investors
Joel Seah
Vesparum Capital
P: +61 3 8582 4800
E: EBRSystems@vesparum.com

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 and is not currently 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 CHESS 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.