ASX ANNOUNCEMENT **20 January 2025**

EBR completes FDA Pre-Approval Inspection and updated guidance on FDA approval timing

Key highlights

- The U.S. Food and Drug Administration (FDA) has completed the manufacturing Pre-Approval Inspection (PAI) with no Form FDA 483 observations
- With the successful conclusion of the PAI, the Premarket Approval (PMA) submission is in its final phase
- EBR now expects regulatory approval on or before 13 April 2025 with commercial launch in H2 2025

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 FDA has completed the manufacturing PAI of EBR's facilities, with no material observations made.

Completion of manufacturing Pre-Approval Inspection and line of sight to final approval

Between 14 and 17 January 2025, the FDA conducted a PAI to verify EBR's manufacturing procedures are compliant with Quality System regulations and ensure EBR can consistently produce medical devices that meet approved specifications. While the PAI report is subject to further FDA review before finalisation, EBR is pleased to note that no Form FDA 483 observations were made (a Form FDA 483 notifies the company's management of observed deficiencies that need to be addressed before approval). EBR believes that FDA regulatory approval should occur on or before 13 April 2025, based upon typical review times. Commercial launch is anticipated in H2 2025.

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

"We are very pleased with the successful conclusion of the FDA's pre-approval inspection audit. These audits are very rigorous, and the result is a clear indication of our team's commitment to following good manufacturing practices.

Given this favourable PAI outcome and the ongoing collaboration with the PMA review, we can now tighten our FDA approval timing expectations, and we believe that the approval should come on or before the 13th of April this year. Although the FDA does not make any firm commitments to precise approval dates, there is every indication that this is a likely timeline."

ENDS

This announcement has been authorised for release by the General 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 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.