ASX ANNOUNCEMENT **1 July 2022**

EBR completes interim enrolment in pivotal SOLVE trial

Key Highlights:

- Successfully completed enrolment in the pivotal SOLVE trial, which represents a significant milestone
- Headline results from the pivotal SOLVE trial is expected to be released in 1Q 2023
- Previous clinical trials of WISE® have exceeded efficacy and safety endpoints of the SOLVE trial
- Targeting PMA submission for FDA approval and US commercial launch in 2H 2023, with an initial annual addressable market of US$2.5 billion
- EBR's WiSE® technology addresses an unmet clinical need and has no direct competition in the marketplace

Sunnyvale, California; 1 July 2022: EBR Systems, Inc. (ASX: **"EBR"**, **"EBR Systems"**, or the **"Company"**), developer of the world's only wireless cardiac pacing system for heart failure, has successfully completed the 183-patient interim enrolment in the pivotal SOLVE-CRT IDE ("**SOLVE**") trial of WiSE®. Following the 6-month follow up of the last patient, EBR expects to release headline results in 1Q 2023.

John McCutcheon, President and CEO of EBR Systems said:
"We are extremely excited to achieve this significant milestone, the completion of interim enrolment in the pivotal SOLVE trial, which is broadly in line with our timing expectations.

Each patient is implanted with WiSE® and followed-up for a period of 6 months. WiSE® offers a unique solution to these patients who would otherwise have no other treatment options and face a high risk of hospitalisation and mortality. Patients worldwide who are unable to receive traditional lead-based cardiac resynchronisation therapy are one step closer to accessing a viable commercial wireless treatment option.

Following previous trials, we remain confident on achieving the key primary endpoints and look forward to sharing our headline results in 1Q 2023 and rapidly move towards commercialisation in key global markets."

The SOLVE trial is evaluating the safety and efficacy of the WiSE® System in up to 300 patients with acute lead failures, chronic lead failures, high-risk upgrades and leadless upgrades. The primary endpoints for the SOLVE trial are:

- **Efficacy endpoint:** >9.3% improvement in heart function measured by a reduction in left ventricular end systolic volume
- **Safety endpoint:** <30% of patients with device or procedure-related complications

Outcomes from previous clinical trials of WiSE® have exceeded the efficacy and safety endpoints set for the SOLVE trial, de-risking the clinical pathway. In addition, EBR has engaged extensively with the FDA, including being awarded Breakthrough Device Designation which provides greater access to the FDA and initial payment coverage. This combination of factors underpins EBR's confidence in the commercialisation of WiSE®.

EBR is targeting pre-market approval (PMA) submission for US Food and Drug Administration (FDA) approval in 2H 2023. The Company estimates an initial annual addressable market of US$2.5 billion for WiSE®. To highlight the significance of this market size - assuming a $1.5 billion initial addressable market in the US in 2024 and an average selling price of US$35,000, just ~10% of the market share will generate potential sales of ~$150m in the first year of commercialisation. EBR plans to launch in Australia and key European markets as well, further unlocking revenue potential and shareholder value.

ENDS

This announcement has been authorised for release by John McCutcheon, President and CEO.

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About EBR Systems (ASX: EBR)

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 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 (including but not limited to the COVID-19 pandemic), 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 submissions 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. Given the current uncertainties regarding the impact of the COVID-19 on the trading conditions impacting the Company, the financial markets and the health services world-wide, investors are cautioned not to place undue reliance on the current trading outlook.

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.