ASX ANNOUNCEMENT **14 March 2022**

Leadless Pacemakers included in SOLVE-CRT IDE Clinical Trial

Key Highlights:

- The US FDA (Food & Drug Administration) has agreed for EBR to include leadless (wireless) pacemakers as a co-implant in the pivotal SOLVE-CRT IDE clinical trial
- If approved for final labelling during the PMA application, the opportunity to pair leadless pacemakers with the WiSE® CRT System to deliver cardiac resynchronisation therapy (CRT) potentially expands EBR's initial addressable market by US$400m in 2024
- SOLVE-CRT remains on track to complete enrolment for interim analysis by H1 2022

Sunnyvale, California; 14 March 2022: EBR Systems, Inc. (ASX: **"EBR"**, **"EBR Systems"**, or the **"Company"**), announces that its pivotal SOLVE-CRT Investigation Device Exemption (IDE) study will be able to include commercially available leadless pacemakers as co-implants for the WiSE® CRT System to deliver cardiac resynchronisation therapy (CRT) for eligible patients.

John McCutcheon, CEO and President of EBR Systems said:

"We are pleased to be able to include leadless pacemakers as co-implants in our pivotal SOLVE-CRT clinical trial. This exciting development has the potential to meet a significant unmet clinical need by providing a solution to physicians whose patients with leadless pacemakers have no other upgrade options.

Leadless pacemakers represent a fast-growing market in cardiac rhythm management and this update makes WiSE® the only device that can potentially support the upgrade of patients currently implanted with a leadless right ventricle pacemaker. If approved for final labelling during the PMA application, the opportunity to pair leadless pacemakers with the WiSE® CRT System to deliver biventricular pacing therapy expands EBR's initial addressable market by US$400m with further growth potential as other leadless pacemakers come to market.

The SOLVE-CRT pivotal trial remains on track to complete recruitment as scheduled. In addition, we look forward to initiating our Totally Leadless CRT (TLC) Study in Australia and Europe, which builds on our dataset of patients treated with WiSE® and leadless pacemakers."

WiSE® is the only leadless, inside-the-left-ventricle-of-the-heart pacemaker that can be used in conjunction with a right ventricle pacemaker to deliver CRT (biventricular pacing) to patients suffering from heart failure. The SOLVE-CRT pivotal trial was originally designed only to include patients with conventional pacemakers (with a lead to the right ventricle). This update expands the patient pool for the SOLVE-CRT trial to include patients with a leadless right ventricle pacemaker, that can be paired with the WiSE® System to deliver CRT.

While future labelling is subject to multiple factors including regulatory approvals, the inclusion of leadless pacemakers in the SOLVE-CRT trial indicates the FDA will consider whether to approve the WiSE® CRT System for use with wireless pacemakers as on-label treatment (*i.e.* FDA-approved treatment option) at the time of PMA (Pre-market Approval) application.

Lastly, the funding requirements, key endpoints, and timing of the SOLVE-CRT trial will not be impacted by this development with enrolment for interim analysis still expected to complete by H1 2022.

ENDS

This announcement has been authorised for release by EBR Systems Board.

For more information, please contact:

Company
John McCutcheon
President & CEO
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 (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.