



## **EBR Systems Receives European CE Mark Approval for World's First Wireless Cardiac Pacing System for Heart Failure**

*New technology could benefit 1.5 million heart failure patients worldwide*

Sunnyvale, Calif. – October 5, 2015 – EBR Systems, Inc., leading innovator in wireless heart stimulation, today announced European CE Mark (Conformité Européenne) approval for its **WiSE™ (Wireless Stimulation Endocardially) Technology**.

EBR Systems' WiSE Technology is the world's only wireless endocardial pacing system for cardiac resynchronization therapy (CRT). CRT is a treatment for heart failure that uses an implantable pacemaker to improve the heart's pumping efficiency by synchronizing the left and right ventricles. Studies have demonstrated successful CRT therapy reduces heart failure symptoms, hospitalizations and mortality. WiSE Technology could potentially benefit 1.5 million of these patients worldwide.

CE Mark approval gives EBR Systems the ability to train and educate physicians in the European Union on the use of the WiSE System, enabling more patients to benefit from this innovative therapy. During the next 12 months, EBR Systems will continue working with leading European clinicians to assess different strategies for optimizing endocardial pacing location that maximize CRT benefits.

Preliminary results of the recently completed SELECT-LV study were presented in mid-May by Mt. Sinai Hospital cardiologist and Professor of Medicine Vivek Reddy, M.D., at the Heart Rhythm Society Scientific Sessions in Boston. In a study of 35 patients who had failed conventional CRT therapy, 97% were implanted successfully with WiSE Technology. Twenty-six of them had reached the six month effectiveness endpoint, with 81 percent improving their clinical composite score which is a measure of symptom improvement. Nine patients had not yet reached the six month follow up.

"A growing body of evidence strongly suggests EBR's WiSE Technology can benefit patients who have failed conventional cardiac resynchronization implants," said EBR Systems CEO Allan Will. "We look forward to working with leaders in the European clinical community to further characterize the benefits of wireless endocardial pacing."

CRT devices have been shown to improve left ventricular function and reduce morbidity and mortality in patients with cardiac synchronization problems. However, conventional CRT devices use wired leads to deliver pacing pulses to the left ventricle. These wires can break or otherwise fail, leading to complications in roughly 5-10 percent of cases. The WiSE Technology is leadless, completely eliminating the need for a pacing wire in the left ventricle.

In addition, approximately 30 percent of patients receiving conventional CRT do not respond to the therapy. Data suggests this is largely due to limitations on where current, market-approved leads can be placed in the heart's venous anatomy to stimulate the left ventricle.

The financial impact of these issues is profound. More than one billion dollars out of \$3.5 billion spent annually on CRT devices provides no patient benefit.

EBR Systems' WiSE Technology consists of a tiny electrode implanted in the left ventricle. With every heartbeat it receives a synchronized ultrasound signal from a small transmitter placed between two ribs. Those sound waves are converted to electrical energy, providing cardiac pacing.

This unique technology eliminates the need for a left ventricular lead and is designed to let the physician place the stimulation point at an optimal, patient specific location inside the left ventricle (endocardially) which may potentially be more effective. Endocardial stimulation is generally considered more like the natural activation pattern of the heart than today's epicardial pacing techniques. Data from multiple sources strongly suggests this can benefit patients and is a potential major advance in left ventricular stimulation.

WiSE is the world's first and only wireless cardiac pacing system for heart failure. In June 2015 it was selected *Favorite Innovation* winner at the annual EUROPACE CARDIOSTIM congress in Milan, Italy.

### **About EBR Systems**

EBR Systems is dedicated to superior treatment of cardiac rhythm disease by providing more physiologically effective pacing through **Wireless Stimulation Endocardially (WiSE)**. The company's patented, proprietary 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 Company's initial product eliminates the need for coronary sinus leads to stimulate the left ventricle in heart failure patients requiring CRT. Future products will address wireless endocardial stimulation for bradycardia and other non-cardiac indications.

The Company's wireless pacing system is not currently available for use in the United States.

### **Media Contact**

Kevin Knight

T: 214-732-9392

[kknightpr@gmail.com](mailto:kknightpr@gmail.com)

<http://ebrsystemsinc/>