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EBR Systems: FDA Approves Wise Leadless Cardiac Pacer

EBR says the US Food and Drug Administration has approved its leadless Wise cardiac resynchronization therapy (CRT) for left ventricular endocardial pacing.

EBR said CRT was “shown to improve clinical status and reduce heart failure hospitalizations and mortality”.

The company said “a material proportion of patients cannot be treated with a lead-based system” showing the need for an alternative for stimulating the left ventricle using CRT.

EBR said its Wise CRT system was designed for patients “left behind by conventional CRT … [and was] the only leadless [product] for left ventricular pacing, designed to work seamlessly with existing pacemakers, defibrillators and CRT devices that provide right ventricular pacing”.

In 2021, Brandon Capital said that the Sunnyvale, California-based EBR Systems Inc had raised $110 million at $1.08 a share to list on the ASX to develop its ‘Wise’ pacemaker, with the funds to be used for a pivotal if the device (BD: Nov 22, 2021).

At that time, Brandon said Wise was the “world’s first and only” wireless, inside-the-left-ventricle-of-the-heart pacing system for heart failure, targeting a US Food and Drug Administration FDA approval in 2023, with the device approved for use in Europe and having FDA breakthrough device designation.

In 2023, EBR said that its 183-patient, pivotal trial of Wise met both the primary efficacy and safety endpoints with statistically significant improvement against pre-set benchmarks, with a reduction of 16.4 percent using its Wise system compared to a performance goal of a reduction of 9.3 percent (p = 0.003) (BD: May 22, 2023).

Last year, the company said it filed the final Wise module to the FDA, including technical specifications and testing data on the device's ability to withstand shocks, heat, cold and other potentially damaging conditions (BD: Aug 29, Dec 9, 2024).

Earlier this year, EBR said the FDA manufacturing inspection was completed, its Wise system had been accepted for expedited reimbursement and it had completed its 100-day meeting with the FDA (BD: Jan 19, 20, 2025).

Today, the company said the FDA had approved Wise for use in adult patients 22 years and older who were indicated for CRT, and had an existing implanted right ventricular pacing system.

EBR said Wise was indicated for patients who had unsuccessful or turned off coronary sinus lead implantations or patients with implemented pacemakers or implantable cardioverter-defibrillators for whom standard CRT upgrades were not advisable due to "high-risk upgrades".

The company said it expected to qualify for two reimbursement schemes effective from October 1, 2025, including the "new technology add-on payment" and "transitional pass-through payment", which would provide payment to cover its selling price.

EBR said it was "expanding its team, strengthening training programs and working with hospitals to simplify implant workflows", with a limited market release to begin in late 2025 and full commercial launch in early 2026.

EBR managing-director John McCutcheon said the company was "thrilled to announce this major milestone for EBR and to share this achievement with our dedicated team, shareholders, partners and stakeholders who have supported us on this journey".

"Securing FDA approval for the Wise CRT system is a transformative moment, marking our transition from clinical development to commercialization," Mr McCutcheon said.

"With FDA approval in hand, EBR is well-positioned to bring our innovative solution to market, delivering real impact to patients and servicing a significant unmet need," Mr McCutcheon said.

"We look forward to executing our commercial strategy and achieving our first revenue in late 2025, paving the way for sustained growth and long-term success," Mr McCutcheon said.

EBR fell 29 cents or 17.2 percent to $1.40 with six million shares traded.