Medtronic News

Medtronic Extravascular ICD meets global pivotal clinical trial's safety and effectiveness endpoints

Late-breaking data presented at ESC Congress 2022 and simultaneously published in *The New England Journal of Medicine* confirms implant procedure safety and defibrillation success

DUBLIN and BARCELONA, Spain, Aug. 28, 2022 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced that its investigational EV ICD™ System – a first-of-its-kind defibrillator with the lead placed under the breastbone, outside of the heart and veins – achieved a defibrillation success rate of 98.7% and met its safety endpoints in a global clinical trial. Findings from the Extravascular Implantable Cardioverter Defibrillator (EV ICD) Pivotal Study were presented as late-breaking science today at the European Society of Cardiology (ESC) Congress 2022 in Barcelona and simultaneously published in *The New England Journal of Medicine*. *Worldwide, the EV ICD system is investigational and not yet approved for sale or distribution.*

The Medtronic EV ICD system is designed to treat dangerously fast heart rhythms that can lead to sudden cardiac arrest (SCA), while avoiding certain risks of traditional, transvenous ICDs because its lead (thin wire) is placed outside the heart and veins, under the breastbone (sternum) using a minimally invasive approach. Placing the lead in this location is designed to help avoid long-term complications that may be associated with leads in the heart and veins, such as vessel occlusion (narrowing, blockage or compression of a vein) and risks for blood infections.

The lead is connected to a device that is implanted below the left armpit (in the left mid-axillary region). Clinical trial participants received the same therapies provided by traditional ICDs, including defibrillation, anti-tachycardia pacing (ATP), and back-up pacing therapies with this single implanted device that is similar in size, shape, and longevity to traditional ICDs.

"We are very encouraged by the high defibrillation effectiveness and strong safety profile of the EV ICD system seen in the study, as we look to deliver less-invasive treatment options for patients at risk of sudden cardiac arrest," said Ian Crozier, MB, CHB, M.D., Christchurch Hospital, Christchurch, New Zealand, who presented the results at ESC Congress 2022. "These results demonstrate the potential for this novel technology to be used as a safe, successful approach for patients with life-threatening arrhythmias."

Study Results: Effectiveness

In the study, the device's effectiveness in delivering defibrillation therapy at implant was 98.7% (298 of 302 patients), surpassing the prespecified performance goal of 88%. These results reflect a greater defibrillation efficacy for the EV ICD than historical transvenous ICD studies;[1-4] comparable efficacy to the subcutaneous ICD despite EV ICD's smaller device size;[5] and a predicted increase in longevity compared to the subcutaneous ICD. Additionally, all discrete spontaneous arrhythmias were successfully treated (18 of 18, 100%).

Further, the efficacy of ATP – which paces the heart to interrupt and terminate a dangerous rhythm, potentially avoiding a defibrillation shock – in the EV ICD study was comparable to ATP efficacy in transvenous defibrillators.[6,7] In total, 33 shocks were avoided by having ATP programmed "on."

Study Results: Safety

The study also exceeded its safety endpoint: at six months, 92.6% of patients (Kaplan-Meier estimate) were free from major system and/or procedure-related major complications such as hospitalization, system revision, or death (compared to the performance goal of 79%; $p<0.001$). There were no major intraprocedural complications, nor any unique complications observed related to the EV ICD procedure or system (compared to transvenous and subcutaneous ICDs).

At six months, 25 major complications were observed in 23 of 316 patients who underwent an implant attempt (7.3%). Twenty-nine patients experienced inappropriate shocks (9.7%, average 10.6 months follow up), most commonly due to P-wave oversensing, which was more frequent in patients implanted early in the study and less frequent among patients implanted later in the study.

"These pivotal data mark the start of a new era in ICD therapy for patients who are at significant risk of dangerously fast heart rhythms," said Alan Cheng, M.D., chief medical officer of the Cardiac Rhythm Management business, which is part of the Cardiovascular Portfolio at Medtronic. "Today's findings are an important clinical milestone toward our goal of delivering a one-system, one-procedure extravascular ICD solution that prevents sudden cardiac arrest while improving the patient experience with a smaller device and moving the lead out of the veins and placing it under the breastbone. The EV ICD system retains the benefits of a completely extravascular system while providing ATP, pause prevention pacing and low defibrillation energy."

The EV ICD Pivotal study is a prospective, multicenter, single-arm, non-randomized, pre-market clinical study that assessed the safety and effectiveness of the Medtronic EV ICD system for patients at risk of sudden cardiac death. The EV ICD Pivotal study enrolled 356 patients at 46 sites in 17 countries in North America, Europe, the Middle East, Asia, Australia and New Zealand. Medtronic has received FDA approval for a Continued Access Study while the agency reviews the company's EV ICD pre-market application.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for all. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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