Medtronic News

Late-breaking data show reliable performance of small-diameter defibrillation lead, the Medtronic OmniaSecure™

Global LEADR clinical trial meets safety and effectiveness objectives; results presented at Heart Rhythm 2024 and simultaneously published in *Heart Rhythm*

DUBLIN and BOSTON, May 17, 2024 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, announced that its investigational OmniaSecure™ defibrillation lead met its primary safety and effectiveness endpoints, exceeding prespecified performance goals, in the global Lead Evaluation for Defibrillation and Reliability (LEADR) Pivotal Trial. Late breaking results were presented at Heart Rhythm 2024 and simultaneously published in the journal *Heart Rhythm*. *Worldwide, the OmniaSecure defibrillation lead is investigational and not yet approved for sale or distribution.*

Implantable cardioverter defibrillators (ICDs) are the gold standard for preventing sudden cardiac death. Yet transvenous defibrillator leads, which are thin wires connected to the ICD and threaded through the veins into the heart muscle, remain the weakest point of the system,[1] given the harsh environment inside the human body where the lead must remain attached and yet flex with millions of heart contractions over a patient's lifetime. Existing defibrillation leads have a large diameter (7-8 French), which can contribute to venous occlusion or tricuspid valve complications. For patients where an extravascular defibrillator may not be appropriate, Medtronic engineers designed the OmniaSecure defibrillation lead based on the Medtronic SelectSecure™ Model 3830 pacing lead, which has offered safe and effective treatment to patients for more than 20 years. By beginning with this highly reliable pacing lead and building a larger lead suitable for defibrillation therapy, the Medtronic OmniaSecure lead is the world's smallest transvenous defibrillation lead (4.7 French, equivalent to the diameter of graphite in a wooden pencil).

LEADR Primary Results: Effectiveness

Defibrillation testing conducted at device implantation in 119 patients was successful in 97.5% of cases. The study exceeded the prespecified efficacy goal of 88%.

LEADR Primary Results: Safety

At six months, 97.1% (Kaplan-Meier estimate) of 657 patients with an implant attempt were free from lead-related major complications such as hospitalization, lead fracture, system revision, or death. The study exceeded the prespecified safety performance goal of 90%. There were no lead-related major complications observed between six and 12 months (average follow up of 12.7±4.8 months).

"The positive results from the LEADR Pivotal trial are a significant advancement for patients at risk of sudden cardiac death who rely on ICDs to deliver life-saving therapy in the event of a dangerous heart rhythm," said George H. Crossley, M.D., Director of the Electrophysiology Lab and Cardiac Research Enterprise, Vanderbilt University Medical Center, Nashville, Tenn., and LEADR Pivotal trial steering committee chair. "Patients with defibrillators are living longer today, and we need to strive for reliable therapy for the lifetime of the patient. This innovative, low-profile defibrillation lead leverages a highly reliable pacing lead design to help achieve this goal, and the unique catheter-based method of implantation helps the physician place the lead in the optimal position for the patient."

The LEADR Pivotal trial is a prospective, multicenter, single-arm, non-randomized, global clinical study that assessed the safety and effectiveness of the Medtronic OmniaSecure defibrillation lead when placed at traditional locations in the right ventricle to achieve defibrillation, sensing, pacing and cardioversion in patients at risk of sudden cardiac death. The study enrolled 675 patients at 45 sites in 17 countries in North America, Europe, Asia, and Australia.

Secondary and Ancillary Results: Reliability

The lead demonstrated reliable performance with zero (0) study lead fractures through an average follow up of 12.7±4.8 months. Medtronic developed and validated an in-vitro model that accurately predicts lead reliability out to 10 years,[2] and then applied that model within the study to predict a fracture-free survival of 99.9% at two years for the investigational OmniaSecure lead. The lead also demonstrated a 97.9% implant success rate, and stable electricals (R-wave, pacing capture threshold, and pacing impedance) through 12 months.

Nearly 12% of patients in the study received appropriate therapy (shock, or anti-tachycardia pacing [ATP]) for dangerously fast ventricular arrhythmias by 14.0±5.0 months. ATP terminated 74.9% of episodes, preventing a shock in 49 patients.

Medtronic plans to present additional reliability model results from the LEADR study in the coming months.

"For 75 years, Medtronic has innovated to bring better life-saving technologies to the patients who need them," said Alan Cheng, M.D., chief medical officer of the Cardiac Rhythm Management business, which is part of the Cardiovascular Portfolio at Medtronic. "Given our history in working with health care providers to design technology for patients with arrhythmias, we applied learnings from our deep experience with both transvenous defibrillation and pacing leads to create the novel OmniaSecure lead, a catheter-delivered lead that can be placed in the desired location. The LEADR study results are an encouraging step forward in achieving the goal of an even more reliable defibrillation lead for patients."

In addition to the LEADR results presented at Heart Rhythm 2024, Medtronic recently initiated the LEADR LBBAP study (Lead Evaluation for Defibrillation and Reliability in Left Bundle Branch Area Pacing), which is assessing the safety and efficacy of the investigational OmniaSecure defibrillation lead when placed at the Left Bundle Branch Area in patients eligible for an ICD or Left Bundle Branch-Optimized Cardiac Resynchronization Therapy (LOT-CRT). Placing the defibrillation lead in the left bundle branch area is being evaluated as an alternative to right ventricular stimulation for sensing, pacing, cardioversion and defibrillation. First implants were recently conducted by Muhammad Afzal, M.D., MBBS, principal investigator at The Ohio State Medical Center Wexner Medical Center, and John Zakaib, M.D., principal investigator at Minneapolis Heart Institute Foundation.

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 our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow Medtronic on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

1 Swerdlow CD, Kalahasty G, Ellenbogen KA. Implantable Cardiac Defibrillator Lead Failure and Management. J Am Coll Cardiol 2016;67:1358-1368

2 Wilkoff, Bruce L., et al. In vitro modeling accurately predicts cardiac lead fracture at 10 years. Heart Rhythm 18.9 (2021): 1605-1612.

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