Abbott Highlights New AVEIR™ Data, Initiates Trial For The Company's Conduction System Pacing Technology

- Late-breaking data from Abbott's groundbreaking first-in-human study demonstrated successful implantation of the company's AVEIR Conduction System Pacing (CSP) leadless pacemaker
- Enrollment has also begun in the ASCEND CSP pivotal clinical trial to evaluate Abbott's investigational CSP Implantable Cardioverter-Defibrillator (ICD) lead
- Conduction System Pacing is an evolving technique specifically designed to deliver pacing to the left bundle branch area of the heart to restore its natural electrical rhythm

SAN DIEGO, April 27, 2025 /PRNewswire/ -- Abbott (NYSE: ABT) today announced late-breaking data from the AVEIR™ Conduction System Pacing (CSP) acute clinical feasibility study, which demonstrated the safety and performance of the investigational AVEIR CSP leadless pacemaker technology. The AVEIR CSP acute clinical feasibility study is the world's first assessment of a leadless pacemaker delivering conduction pacing to the heart's left bundle branch (LBB) area. CSP is a novel pacing approach that targets the LBB area by enabling pacing that mimics the heart's natural electrical rhythm.

The results were presented as a late-breaking clinical trial at the Heart Rhythm Society's (HRS) 46th annual meeting in San Diego (April 24-27, 2025) and simultaneously published in the *Heart Rhythm Journal*.

The AVEIR CSP acute clinical feasibility study demonstrated successful implantation of the AVEIR CSP leadless pacemaker deep into the wall separating the left and right chambers of the heart, many achieving left bundle branch area pacing (LBBAP). All study participants received the AVEIR ventricular (VR) leadless pacemaker at the end of the procedure.

"For the first time, we have successfully demonstrated the feasibility of a leadless pacing system to facilitate conduction system pacing in the left bundle branch area of the heart, offering a novel approach to pacing therapy," said Vivek Y. Reddy, M.D., director of cardiac arrythmia services at Mount Sinai Hospital, New York, and the study's principal investigator. "Leadless pacing has already demonstrated significant benefits to patients. This new groundbreaking approach may enable a more physiologic way of stimulating the heart with Abbott's AVEIR CSP leadless pacemaker system, giving patients more treatment options."

Conduction System Pacing Momentum within Abbotts Cardiac Rhythm Management Portfolio

To maximize potential benefits to patients, Abbott is developing two unique approaches to conduction system pacing, focusing on targeting the LBB area with both traditional pacing and leadless technology.

In addition to completing the AVEIR CSP acute clinical feasibility study, Abbott recently started enrolling the first patients in the ASCEND CSP pivotal clinical trial. This trial will evaluate the safety and effectiveness of the investigational CSP Implantable Cardioverter-Defibrillator (ICD) lead three months post-implant and will enroll up to 414 people at up to 70 sites worldwide, including in the United States, Canada, Europe and the Asia-Pacific region. This uniquely designed lead aims to reduce complications, enhance pacing precision, and improve long-term outcomes for patients requiring ICD therapy.

Abbott's UltiPace™ Pacing Lead is the first FDA-approved stylet-driven lead indicated for left bundle branch area placement. Recently, the U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designations to both Abbott's AVEIR CSP leadless pacemaker system and the CSP ICD lead for LBBAP. Breakthrough Device Designation expedites the review of innovative technologies that can improve the lives of people with life-threatening or irreversibly debilitating diseases or conditions.

"Our ongoing innovation in conduction system pacing has the potential to drive meaningful advancements, offering new potential treatment options for people with slow or irregular heart rhythms," said Randel Woodgrift, senior vice president of Abbott's cardiac rhythm management business. "These two clinical studies underscore the critical importance of conduction system pacing in the left bundle branch area both with our breakthrough leadless technology and uniquely designed lead, enabling physicians to better treat a broader range of patients who require pacemaker and ICD therapies."

About Abbott

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 114,000 colleagues serve people in more than 160 countries.

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