Abbott Announces First-In-World Leadless Pacing Procedures In The Left Bundle Branch Area Of The Heart

- Abbott's investigational AVEIR™ Conduction System Pacing (CSP) leadless pacemaker system is specifically designed to deliver pacing to the left bundle branch area, activating the heart's natural conduction system
- The device has received U.S. Food and Drug AdministrationBreakthrough Device Designation, which expedites the review of innovative technologies
- By creating a new pacing approach for the left bundle branch area of the heart, Abbott continues to pursue technologies to revolutionize care for people with slow or irregular heart rhythms

ABBOTT PARK, Ill., Dec. 17, 2024 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the successful completion of the world's first in-human leadless left bundle branch area pacing (LBBAP) procedures using the company's investigational AVEIR™ Conduction System Pacing (CSP) leadless pacemaker system, as part of a feasibility study. These procedures mark the first time a leadless pacemaker has been implanted into the left bundle branch area, a key part of the heart's electrical conduction system, designed to mimic the heart's natural beat, offering people with slower-than-normal heart rhythms a new potential treatment option.

The landmark procedures were part of the prospective Leadless CSP feasibility study, which evaluates the acute safety and performance of the investigational AVEIR CSP leadless pacemaker system. The procedures were completed in the fall of 2024 by Professor Petr Neužil, M.D., Ph.D., head of the department of cardiology at Na Homolce Hospital inPrague, Czech Republic, and the site's principal investigator, and Vivek Y. Reddy, M.D., director of cardiac arrhythmia services at Mount Sinai Hospital, New York, and the study's principal investigator.

"While both conduction system pacing and leadless pacing provide distinct benefits to many patients, they have been separate options – until now," said Devi Nair, M.D., director of cardiac electrophysiology at St. Bernards Medical Center,Jonesboro, Arkansas, and a key contributor to the study. "For the first time, the study of the AVEIR CSP leadless pacemaker system evaluates a pioneering approach that directly targets the left bundle branch area, combining the advantages of conduction system and leadless pacing technologies."

CSP is an evolving technique in which a traditional pacemaker wire is implanted deep into the wall separating the left and right chambers of the heart. This approach activates the left bundle branch area enabling physiological pacing which mimics the heart's natural electrical current. As a result, physicians believe this pacing approach could improve the physiological response from the heart compared with other pacing options.

The seamless integration of CSP procedures with leadless pacemaker technology has the potential to deliver unique benefits over traditional pacemakers. Leadless pacing systems eliminate the need for cardiac leads and a pulse generator under the skin and avoid long-term risks of lead- and pocket-related complications. As a result, leadless pacemakers like the AVEIR family of products are a potential solution for some of the complications often associated with traditional pacemakers.

The U.S. Food and Drug Administration (FDA) has grantedBreakthrough Device Designation to explore the use of Abbott's AVEIR CSP leadless pacemaker system 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.

"Bringing our proven leadless pacemaker technology to the left bundle branch area has great potential to be another transformative moment in cardiac care," said Randel Woodgrift, senior vice president of Abbott's cardiac rhythm management business. "By continuously innovating our approach to pacing, Abbott is revolutionizing care for millions of people living with slow or irregular heart rhythms."

Completing the research team were Rahul Doshi, M.D., chief cardiac arrhythmia group at HonorHealth,Scottsdale, Arizona; and Shephal Doshi, M.D., executive director at Heart and Vascular Institute, Providence Saint John's Health Center, Santa Monica, California -- key contributors in the feasibility study and completion of the procedures.

About the AVEIR Leadless Pacemaker System
Abbott's AVEIR dual chamber (DR) leadless pacemaker system received FDA approval in June of 2023. Through its novel i2i™ (implant-to-implant) technology, the AVEIR DR leadless pacemaker system provides synchronized pacing by utilizing high-frequency electrical impulses to relay messages between co-implanted leadless pacemakers via the naturally conductive characteristics of the body's blood and tissue. The AVEIR CSP leadless pacemaker system is in development and not commercially available.

To find more information on AVEIR leadless pacemakers, visit: https://bit.ly/3zcmkRJ.

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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