ABBOTT'S NEW LEADLESS PACEMAKER SYSTEM MEETS PRIMARY ENDPOINTS IN PIVOTAL TRIAL

-- New, late-breaking data from the Leadless II IDE study confirm the Aveir™ leadless pacemaker achieved the pre-specified primary endpoints in treating patients with certain types of abnormal heart rhythms

-- Abbott's Aveir system is the world's only leadless pacemaker specifically designed to be retrieved when the device needs to be replaced or if a patient's therapy needs to be changed

-- Abbott's investigational Aveir leadless pacemaker is currently being evaluated for FDA approval

ABBOTT PARK, Ill., Nov. 12, 2021 /PRNewswire/ -- Abbott (NYSE: ABT) today announced new, late-breaking data from the global Leadless II IDE study evaluating Abbott's investigational Aveir leadless pacemaker in patients with certain abnormal heart rhythms. The data shows the Aveir device met its pre-specified primary endpoints and suggest that the Aveir system, once approved, could offer new benefits for patients who require the use of a pacemaker to treat slow heart rhythms.

The findings were presented today in a late-breaking session at the annual Scientific Sessions of the Asia Pacific Heart Rhythm Society (APHRS) and simultaneously published in the *Journal of the American College of Cardiology: Clinical Electrophysiology*. The data from the study has also been submitted to the U.S. Food & Drug Administration as the Aveir leadless pacemaker is evaluated for U.S. approval.

People who experience slower-than-normal heart rates may receive a pacemaker to restore a more normal heart rate. Yet unlike traditional pacemakers, leadless pacemakers do not require an incision in the chest to implant the device or insulated wires – known as cardiac leads – to deliver energy to the heart. Instead, leadless pacemakers are implanted directly into the heart's right ventricle via a minimally invasive procedure, requiring no cardiac leads to deliver therapy.

"The new Aveir pacing system holds the potential to help us advance treatment for patients who need a pacemaker but where physicians are concerned about more invasive surgery or in circumstances where we believe a patient's therapy needs may change in the future and where retrievability will be a critical device feature," said Dr. Vivek Y. Reddy, Helmsley Trust professor of medicine, director of cardiac arrhythmia services, Mount Sinai Hospital.

Under the Leadless II trial design, primary safety and efficacy endpoints were analyzed in the 200 patients enrolled in 43 centers in the U.S., Canada and Europe. Patients were followed for six weeks. Results of the study showed:

- Successful implant of the Aveir leadless pacemaker in 98% of patients.
- At six weeks post-implant, 96% of patients met the safety endpoint of no serious adverse device effects and 95.9% achieved the efficacy endpoint of acceptable therapy delivered to the patient (known as therapeutic pacing threshold and sensing amplitude).
- Additionally, physicians were able to accurately position the device either the first time or with a single repositioning in 96% of clinical cases.

"As we developed the Aveir leadless pacemaker platform, our fundamental guiding principle was to design a device with extended battery life that could be retrievable, expandable to incorporate future innovation and provide improved patient outcomes with a minimally-invasive implant procedure," said Randel Woodgrift, senior vice president, Cardiac Rhythm Management, Abbott. "The results of the Leadless II study are a strong indicator that once the device is approved, the Aveir system can help physicians manage the care of patients with certain abnormal heart rhythms."

ABOUT THE LEADLESS II STUDY

The Leadless II IDE study is a prospective, non-randomized, multicenter study designed to evaluate the clinical safety and efficacy of the Aveir leadless pacemaker in patients who were indicated for a VVI(R) – or ventricular demand pacing – pacemaker, which stimulates the heart only if the heart rate falls below a set level.

For the primary endpoint analyses, all patients were followed for six weeks post-implant to evaluate potentially serious adverse device effects. During this time, efficacy was measured as acceptable pacing capture threshold (≤ 2.0 V at 0.4 msec) and sensing amplitude (R wave ≥ 5.0 mV, or a value equal to or greater than the value at implantation).

The Aveir leadless pacemaker system is being investigated as part of the Leadless II IDE – a global study – and is not yet commercially available. The device design specifications are subject to change pending regulatory review.

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 109,000 colleagues serve people in more than 160 countries.

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