Abbott Receives FDA Approval For Aveir™ VR Leadless Pacemaker System To Treat Patients With Slow Heart Rhythms

- Abbott's Aveir single chamber (VR) pacing system is the world's only leadless pacemaker with a unique mapping capability to assess correct positioning prior to placement
- Aveir VR has an increased projected battery life that can be up to two times longer than other commercially available leadless pacemakers when using the International Organization for Standardization (ISO) standard settings
- Aveir VR is specifically designed to be retrieved when therapy needs evolve or the device needs to be replaced

ABBOTT PARK, Ill., April 4, 2022 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved the Aveir™ single-chamber (VR) leadless pacemaker for the treatment of patients in the U.S. with slow heart rhythms. This marks significant advancement for patient care and brings new, never-before-seen features to patients and their physicians.

The Aveir leadless pacemaker is implanted directly inside the heart's right ventricle via a minimally invasive procedure to treat slower-than-normal heart rates. Unlike traditional pacemakers, leadless pacemakers do not require an incision in the chest to implant the device or cardiac leads to deliver therapy.

The device has a unique mapping capability designed to allow physicians to measure electrical signals within the heart and determine the correct placement of the device before final implantation. It has an increased projected battery life that can be up to two times longer than other currently commercially available leadless pacemakers when using International Organization for Standardization (ISO) standard settings.[1] In addition, the device is the only leadless pacemaker designed to be retrieved if therapy needs evolve.

"The Aveir leadless pacemaker offers an exciting option for the treatment of people with cardiac arrhythmias. Leadless pacemakers address known complications associated with traditional pacemakers. In addition, the Aveir leadless pacemaker brings unique innovations we've been seeking, such as the ability to ensure electrical performance before we commit to placement," said Rahul Doshi, M.D., Director of Electrophysiology, Honor Health. "Abbott's leadless pacemaker addresses the need for a single-chamber device that accommodates any therapy path for a patient through Aveir's retrieval capability and extended battery longevity."

This approval is supported by data from the global LEADLESS II phase 2 investigational device exemption (IDE) study evaluating Aveir VR in patients with certain abnormal heart rhythms. The results showed the device met its pre-specified primary endpoints. The findings were presented at the annual Scientific Sessions of the Asia Pacific Heart Rhythm Society (APHRS) in November 2021 and simultaneously published in the *Journal of the American College of Cardiology: Clinical Electrophysiology*.

"The Aveir VR leadless pacemaker was designed to make the implantation and retrieval processes as seamless as possible for physicians and provide improvements over existing options," said Randel Woodgrift, senior vice president, Cardiac Rhythm Management, Abbott. "Our goal is to continue to build on the success of Aveir to provide more first-of-their-kind products in the future, revolutionizing how abnormal heart rhythms are treated."

About Aveir VR
Abbott's Aveir™ single chamber (VR) leadless pacemaker is approved for the treatment of patients in the U.S. with slow heart rhythms. The world's only leadless pacemaker with a unique mapping capability to assess correct positioning prior to placement, Aveir VR is specifically designed to be retrieved if therapy needs evolve.

For U.S. important safety information on the Aveir VR leadless pacemaker, visit https://www.cardiovascular.abbott/us/en/hcp/products/cardiac-rhythm-management/pacemakers/aveir-vr-leadless-pacemaker/isi.html.

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 113,000 colleagues serve people in more than 160 countries.

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[1] Tested at VVIR 60 bpm, 2.5 V, 0.4 ms, 600 ohms at 100% pacing

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