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V-Wave's Interatrial Shunt receives FDA Breakthrough Device Designation for Heart Failure

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V-Wave Ltd., a privately held medical device company developing novel implantable interatrial shunt devices has announced that the U.S. Food and Drug Administration (FDA) has just granted the company a Breakthrough Device Designation for its interatrial shunt for Heart Failure (HF).

V-Wave's minimally invasive, implanted interatrial shunt is being evaluated in a global, randomized, controlled, double-blinded, 500 patient pivotal IDE trial called RELIEVE-HF. The study is enrolling advanced HF patients with preserved or reduced left ventricular ejection fraction who remain symptomatic despite the use of guideline directed medical and device therapies.

FDA Breakthrough Device Designation is granted to devices that have the potential to offer a "more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases."

The program aims to provide patients and health care providers with more timely access to medical devices "by speeding up their development, assessment and review," including prioritized review all the way through market approval.

This process facilitates interactive and timely communication between the sponsor and the FDA, as well as the potential to balance pre- and post-market data requirements. To make patient access timelier and more available, the Centers for Medicare and Medicaid Services (CMS) has announced that it is developing a means to expedite reimbursement pathways and provide increased payments for medical devices designated as breakthrough.

"This FDA Breakthrough Device Designation emphasizes the critical and unmet need for novel therapeutic devices for HF," noted heart failure cardiologist and V-Wave Chief Medical Officer, William T. Abraham, MD.

"More than 6 million people suffer from chronic heart failure in the US. HF remains a leading cause of acute hospitalization in the Medicare age group. Despite decades of advances in therapy, heart failure patients continue to deteriorate, enduring disabling symptoms, having a poor quality of life, diminished exercise tolerance, and a markedly reduced life expectancy. The V-Wave Shunt relieves excessive pressure in the left-side of the heart thereby reducing the build-up of fluid in the lungs, which is known to be the most common reason for HF hospitalizations and exercise limitation."

V-Wave CEO Neal Eigler, MD, added, "We are thrilled to be able to work even more closely with the FDA to accelerate the introduction of potentially clinically impactful therapies in the USA. This breakthrough designation provides V-Wave with additional options for FDA communication that will facilitate collaboration, as well as a prioritized review of submissions and marketing applications. The potential for early CMS support for this program, makes our Breakthrough Designation a double-win for HF patients who need access to novel therapies as quickly as possible."