ABBOTT INITIATES STUDY TO EVALUATE ABLATION AS A FRONTLINE TREATMENT FOR PATIENT'S SUFFERING FROM A COMMON BUT COMPLEX CARDIAC ARRHYTHMIA

LESS-VT Study is the first U.S. clinical trial to evaluate the safety and effectiveness of ablation treatment for patients with monomorphic ventricular tachycardia, a common heart rhythm disorder

ABBOTT PARK, Ill., Nov. 19, 2018 — Abbott today announced it has initiated the industry's first trial to evaluate ablation treatment for ventricular tachycardia (VT), a common heart rhythm disorder that causes the lower chambers of the heart to beat faster than normal. The LESS-VT study, which is currently enrolling patients, will evaluate the safety and effectiveness of ablation delivered by Abbott's FlexAbility™ Ablation Catheter, Sensor Enabled™, for the treatment of monomorphic ventricular tachycardia (MMVT) for people who are unresponsive to drug therapy.

Over the next two years, Abbott expects to enroll more than 600 patients at 35 sites in the U.S. and Europe. The results will help expand the health care community's understanding of using radiofrequency ablation therapy as a frontline treatment for patients suffering from ventricular tachycardia. The study is also designed to support Abbott's submission for Food and Drug Administration approval of an indication expansion for the company's ablation therapy.

"For some patients with sustained monomorphic ventricular tachycardia, drug therapy is an ineffective treatment option," said Paolo Della Bella, M.D., an electrophysiologist on the LESS-VT trial steering committee and head of the EP Laboratories and Arrhythmia Department at San Raffaele Hospital in Milan, Italy. "We want to build a body of clinical evidence that establishes ablation as a therapy solution for people with ischemic and non-ischemic MMVT."

MMVT, the most common form of ventricular tachycardia, is a heart rhythm disorder where the heart's lower chambers – known as ventricles – beat abnormally fast and out of sync with the upper chambers. When ventricular tachycardia occurs, the heart does not fill with enough blood between beats to meet the body's needs. A sustained episode can quickly develop into ventricular fibrillation (VF) which may lead to sudden cardiac arrest and can be life-threatening.

Pharmaceuticals are sometimes used to treat sustained MMVT in patients, but for some patients they are not effective. For people not responsive to drug therapy, current treatment options are limited. Alternatively, cardiac ablation is a minimally invasive approach that can treat abnormally fast heartbeats by creating lesions in small areas of heart tissue that a physician has identified as causing the arrhythmia. As a result, the tissue is no longer capable of conducting or sustaining the arrhythmia.

In addition to the FlexAbility SE ablation catheter, Abbott also recently introduced the Advisor HD Grid mapping catheter to support treatment of conditions such as MMVT. The Advisor HD Grid catheter is designed to capture information — such as the direction of cardiac signals — often missed with traditional mapping catheters. Advisor HD Grid offers physicians a unique grid configuration that captures this critical information and enables the creation of high-density maps of cardiac tissue to support treatment for patients.

"Data suggests treating people with arrhythmias, including sustained MMVT, reduces the risk of developing other complications and hospitalizations," said Srijoy Mahapatra, M.D., FHRS, medical director of Abbott's electrophysiology business. "The goal of the LESS-VT study is to provide physicians with relevant data to help them determine the most effective treatment option for their patients with monomorphic ventricular tachycardia. With recent advances in Abbott's unique ablation tools and cardiac mapping technology, we aim to uncover treatment strategies to benefit patients so they can return to living healthy, full lives."

About the LESS-VT IDE Trial:

The LESS-VT trial is a two-arm (a non-ischemic, non-randomized arm and an ischemic, randomized arm), multicenter, clinical investigation designed to evaluate the safety and effectiveness of the FlexAbility SE catheter for ablation in patients with drug-refractory, sustained, ischemic and non-ischemic monomorphic ventricular tachycardia (MMVT). The primary effectiveness endpoint is the rate of freedom from MMVT at six months and a new or increased dose of Class I or III antiarrhythmic drug at six months.

For more information about the LESS-VT trial, please visit clinicaltrials.gov.

About Abbott:

At Abbott, we're committed to helping you live your best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 99,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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