Study Finds 89% Of Patients Treated For Persistent Atrial Fibrillation Using Abbott's Ablation Device Remain Symptom-Free For At Least 15 Months

- Treatment with the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ resulted in patients with persistent atrial fibrillation experiencing an improved quality of life
- The catheter is part of Abbott's suite of electrophysiology solutions designed to improve procedures to address cardiac arrhythmias

ABBOTT PARK, Ill., April 29, 2022 /PRNewswire/ -- Abbott (NYSE: ABT) today announced results from the PERSIST-END study, which showed that nearly nine out of 10 patients (89%) treated for persistent atrial fibrillation (AFib) with the company's TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ (TactiCath SE) remained symptom-free for up to 15 months following the procedure. The data, which is being presented at the annual meeting of the Heart Rhythm Society April 29 – May 1, also showed that due to the more effective therapy, patients reported significant quality-of-life improvements and more than 50% reduction in the use of health care resources.

Millions of Americans are affected by abnormal heart rhythms, known as arrhythmias, caused by breakdowns in the electrical pathways of the heart. Left untreated, these breakdowns can lead to erratic heartbeats or cause the heart to beat too fast or too slow, which can dramatically impact a person's health. AFib, the most common arrhythmia, is a condition in which the heart's chambers are out of sync, causing them to beat in a rapid and chaotic fashion. Persistent AFib is a type of arrhythmia that lasts anywhere from one week to a year. If left untreated, AFib may eventually lead to heart failure or stroke.

"Like many arrhythmias, persistent AFib can be difficult to treat and to date we have had relatively few approaches approved specifically to treat this condition," said Douglas Gibson, M.D., site principal investigator and director of cardiac electrophysiology at Scripps Clinic and the Prebys Cardiovascular Institute in San Diego, Calif. "The results of the PERSIST-END study show that Abbott's TactiCath SE can help physicians ensure the majority of our persistent AFib patients will remain symptom-free following their therapy and will go on to experience dramatic improvements in their quality of life."

AFib is categorized into three types: paroxysmal, persistent or long-standing persistent. Paroxysmal is defined as an abnormal heart rhythm that lasts for less than a week, persistent lasts between one week to a year, and long-standing persistent lasts longer than a year. Approximately half of patients with AFib have a long-standing persistent heart rhythm issue while the remaining 50% are equally divided between paroxysmal and persistent.[1] TactiCath SE was previously approved for paroxysmal AFib and the data from the PERSIST-END study supported approval of the additional indication in persistent AFib in 2021.

TactiCath SE is used as part of a cardiac ablation procedure, a minimally invasive method that allows doctors to treat the condition at the source by selectively disrupting the area of the heart generating abnormal heart beats. The catheter provides doctors essential and immediate feedback when the tip of the ablation catheter connects with the tissue within the heart, which can help improve accuracy and consistency of the procedure. It is used in conjunction with Abbott's EnSite™ X EP System, the Advisor™ HD Grid Mapping catheter, and EnSite Omnipolar Technology (OT).

"Ablation therapy is an increasingly important option for people living with cardiac arrhythmias because it allows physicians to treat the cause of the arrhythmia at its source. However, it can be a challenging procedure because the right amount of pressure needs to be applied to the heart wall to be effective, but not so much as to cause other problems," said Christopher Piorkowski, M.D., chief medical officer of Abbott's electrophysiology business. "We developed TactiCath SE to provide clear information on whether the device is making contact with the heart wall and whether the pressure is enough to achieve the therapeutic goals. The outcomes are clear – the system delivers safe and effective results."

About PERSIST-END
PERSIST-END was a prospective, multi-center, single-arm clinical trial that included 224 patients from 21 investigational sites in the U.S. and Australia conducted from 2018 to 2021. Patients were evaluated for 15 months following the cardiac ablation procedure for safety, efficacy, and quality of life measures.

The primary safety endpoint for the trial was defined as the rate of primary device and/or procedure-related serious adverse events (SAEs) occurring within seven days of any ablation procedure. Primary efficacy was defined as freedom from documented AFib, atrial flutter or tachycardia >30 seconds or longer, new or increased dose of Class I/III antiarrhythmic drug (AAD), repeat ablation, and cardioversion through 15 months of follow-up.

The trial met all of its primary safety, effectiveness and quality of life endpoints. The rate of serious adverse events was 3.1%, which is consistent with other studies in the persistent AFib population. In addition, the overall primary effectiveness endpoint found that 61.6% of patients remained free from arrhythmia recurrence, any new or increased Class I/III AAD, repeat ablation or cardioversion.

The study further found that participants reported that their Atrial Fibrillation Effect on the QualiTy-of-life (AFEQT) score increased by more than 27 points after three months and more than 32 points after 15 months – a clinically important difference resulting in an average 91.9 quality of life score on a 100-point scale 15 months after the procedure. Similarly, the patients' average annual overall cardiovascular-related health care utilization decreased by 53% in the 15 months following ablation compared to pre-ablation utilization.

About Cardiac Ablation

When physicians use ablation to treat cardiac arrhythmias, long flexible tools — called catheters — are inserted into the heart to study the arrhythmia and to deliver radio frequency energy. Heat generated from the radio frequency energy disrupts the cells that are creating the abnormal heart rhythm. As a result, this tissue is no longer capable of conducting or sustaining the arrhythmia.

For U.S. important safety information on the TactiCath Contact Force Ablation Catheter, Sensor Enabled, visit: https://www.cardiovascular.abbott/us/en/hcp/products/electrophysiology/ablation-technology/tacticath-se-ablation-catheter/indications-safety-warnings.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] Zoni-Berisso M, Lercari F, Carazza T, Domenicucci S. Epidemiology of atrial fibrillation: European perspective.*Clin Epidemiol*. 2014;6:213-220. Published 2014 Jun 16. doi:10.2147/CLEP.S47385

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