

ABBOTT SEEKS BETTER TREATMENT OPTIONS FOR PATIENTS WITH BOTH ATRIAL FIBRILLATION AND HEART FAILURE WITH NEW TRIAL

- A new, first-of-its-kind study known as TAP-CHF leverages expertise across Abbott's cardiovascular portfolio to optimize treatment for patients suffering from both AFib and heart failure

- The trial will utilize Abbott technology including cardiac ablation and sensors to monitor for both pulmonary artery pressure and abnormal heartbeats

- Historically, treating patients with both AFib and heart failure has been challenging, with few effective treatments or options to adequately manage both conditions simultaneously

ABBOTT PARK, Ill., May 6, 2021 /PRNewswire/ -- Abbott (NYSE: ABT) today announced a new trial focused on improving the treatment for people simultaneously battling both atrial fibrillation (AFib) and heart failure. The first-of-its-kind trial aims to provide new insights into more effective treatment for patients with AFib and heart failure, a complex combination that has historically presented significant challenges to physicians.

For many patients, cardiovascular disease can be exacerbated by comorbidities – additional problems requiring simultaneous management that make treatment of either condition more challenging. Clinical trials assessing therapies that can be deployed in tandem to better manage cardiovascular comorbidities are also rare. Few companies offer therapies across a clinical care spectrum that allows for the unique trial designs that can best provide physicians the insight they need to change the course of future care decisions.

The new TAP-CHF trial (Evaluating the **T**reatment of **A**trial Fibrillation in **P**reserved **C**ardiac Function **H**ear**F**ailure) aims to discover better management options for patients with AFib and heart failure with preserved ejection fraction (HFpEF) – a type of heart failure in which the heart cannot relax and fill with blood effectively prior to pumping. Combined, these conditions can be very difficult for doctors to control as they put increased pressure on the pulmonary arteries, which provide blood flow from the heart to the lungs. For patients, the two conditions increase the risk of stroke, hospitalization or even death. Abbott is a leader in developing medical devices for treating both heart failure and arrhythmias like AFib and is investigating better treatment options for these patients with the goal of yielding better outcomes and improved quality of life.

"Cardiovascular patients often have more than one heart condition. We believe that we can best help those patients live longer and better lives by providing their doctors improved therapy approaches that address the entirety of their heart disease," said Philip Adamson, M.D., chief medical officer for Abbott's heart failure business. "Trials that look at complex heart conditions together promise to offer new insights and will make a tremendous difference in the outcomes of our patients now and into the future."

EVALUATING PATIENTS IN NEW WAYS

The TAP-CHF trial will manage patients in two phases to better help physicians understand the impact of monitoring fluctuations in pulmonary pressure.

- In the first phase, physicians will deploy either cardiac ablation or medication to control erratic heart rhythms in AFib patients with a history of heart failure.
- Following treatment for AFib, all patients will receive the Abbott [Confirm Rx™](#) insertable cardiac monitor to help physicians monitor for recurrent abnormal heart rhythms.
- In the second phase, physicians will randomize patients to receive typical clinical management for heart failure based on symptom changes or to heart failure management guided by data from Abbott's [CardioMEMS™ HF System](#), a pulmonary pressure sensor that can provide doctors with an early warning of worsening heart failure.

Abbott expects the TAP-CHF trial to enroll up to 100 patients at 10 trial sites in the U.S. At the end of the trial, outcomes of patients who had their heart failure management guided by data from the CardioMEMS HF System will be compared to those who received standard of care (medicine) for their heart failure to determine which patient group had better outcomes based on recurrence of AFib, hospitalization or death. The trial will also provide insights into the effect of catheter ablation in patients with HFpEF.

"Heart failure in patients with preserved ejection fraction is a major unsolved public health challenge worldwide, with few effective avenues of treatment. This is compounded by the fact that AFib affects nearly half of these patients, increasing the risk of mortality and increased hospitalization," said Sanjeev Saksena, M.D., principal investigator of the TAP-CHF trial, clinical professor of medicine at the Rutgers' Robert Wood Johnson Medical School and medical director at the Electrophysiology Research Foundation. "In partnership with innovation leaders such as Abbott, we've made significant progress in how we treat patients battling AFib, and we've also made progress in how we manage heart failure. But to continue to treat people more effectively who are facing both conditions, we need innovative treatment strategies, fresh insights and confirmation of new therapeutic approaches."

The TAP-CHF trial is an investigator-initiated phase 4, sequential, randomized, open label and multicenter prospective comparative study to address the major health challenge presented by HFpEF and AFib. The trial is

administered by the Electrophysiology Research Foundation and involves worldwide leaders in deploying innovative therapies for both conditions.

For U.S. important safety information for the CardioMEMS HF System, visit:

<https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/pulmonary-pressure-monitors/cardiomems/indications-safety-warnings.html>

For U.S. important safety information for the Confirm Rx, visit:

<https://www.cardiovascular.abbott/us/en/hcp/products/cardiac-rhythm-management/insertable-cardiac-monitors/confirm-rx/indications-safety-warnings.html>

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