Abbott Initiates New Clinical Trial To Improve Outcomes In Patients With Advanced Heart Failure

- The first-of-its-kind TEAM-HF study seeks to improve clinical outcomes in patients with worsening heart failure
- Trial establishes new, objective criteria to identify patients most at risk for developing end-stage heart failure and potentially offer life-saving therapeutic options sooner in their disease progression

ABBOTT PARK, Ill., Oct. 24, 2024 /PRNewswire/ -- Abbott (NYSE: ABT) today announced a new, first-of-its-kind clinical trial designed to improve outcomes in patients with worsening heart failure who could benefit from advanced therapy options. The TEAM-HF trial, which is planned to enroll up to 850 patients across 75 sites worldwide, will measure pulmonary artery pressures (PAP) using Abbott's CardioMEMS™ HF System to objectively identify advanced heart failure patients at high risk of mortality who could benefit from a life-saving HeartMate 3™ left ventricular assist device (LVAD, or heart pump) earlier in their disease progression.

Heart failure is a progressive condition that occurs when the heart can't circulate blood efficiently, resulting in symptoms such as fatigue, breathlessness, and swollen ankles. Approximately 6.7 million people in the United States have heart failure, and that number is expected to rise to 8.5 million by 2030.[1] While there are currently evidence-based guidelines for treating patients with advanced therapies (either LVADs or heart transplantation) when they are in end-stage heart failure, there are fewer objective criteria for identifying patients who are earlier in their disease progression. This can result in patients being offered advanced therapies such as an LVAD when their heart failure has become too advanced, leading to poorer outcomes, and even death.

"The goal of the TEAM-HF trial is simple in concept but critical to the future care of patients. We want to break down patient care silos, offering a unified effort to not only improve the diagnosis of advanced heart failure, but also enable rapid access to life saving heart pumps. This study aims to take the guess work out of deciding when a patient has reached the ideal time for LVAD implementation," said Jennifer Cowger, M.D., medical director of mechanical circulatory support and section head of the advanced heart failure program at Detroit-based Henry Ford Health, and one of the national co-principal investigators for the TEAM-HF trial. "Too many patients are not receiving timely access to this life-saving therapy and are needlessly dying of heart failure. The importance of patient access to multidisciplinary heart failure care is embodied in the trial acronym - TEAM-HF - and we feel this study will be instrumental in helping providers identify patients who may benefit from a heart pump earlier in their care journey."

TEAM-HF: Deploying a New Approach to Therapy Decisions
Patients with end-stage heart failure who rely on IV-administered heart failure medications designed to strengthen the heart's blood pumping ability have poor outcomes with a median survival of nine months.[2] Guideline recommendations for treating patients who depend on these medications include advanced therapies such as LVADs. However, patients who are not yet dependent on medication also have a poor clinical prognosis but are often not referred for these advanced options until their symptoms worsen. This delay is partly due to the lack of objective measures to identify patients who would most benefit from an LVAD.

The TEAM-HF trial will deploy a novel approach to assess the impact of earlier interventions in patients with worsening heart failure. Investigators will first examine PAP data securely collected from participants using Abbott's CardioMEMS™ HF System. The CardioMEMS sensor, placed in the pulmonary artery during a minimally invasive outpatient procedure, monitors pulmonary artery pressure changes over time. If pressures do not go down with guideline directed medical therapy, the TEAM-HF trial will seek to prove that such patients will benefit from advanced therapies. These patients will be randomized to receive either the HeartMate 3 LVAD implant or continued treatment with their existing heart failure medications. Patients whose existing medications reduce their PAP levels will enter a single arm registry where they will continue to be managed based on data from their CardioMEMS sensor.

"As the only healthcare company in the world that has developed medical devices designed to treat people at each stage of heart failure, our hope is that the TEAM-HF study will revolutionize care management for these patients and their families. Getting people on a heart pump more quickly could mean more time spent out of the hospital and with loved ones," said Keith Boettiger, vice president, Abbott's heart failure business. "By having more objective methods to accurately gauge heart failure progression and refer people to receive this life-saving therapy faster, healthcare experts will be able to provide patients with improved survival rates and quality of life based on the anticipated results of the TEAM-HF study."

Enrollment in TEAM-HF will commence shortly at sites across the U.S. The trial's powered primary and secondary endpoints will be evaluated at two years, with long-term follow up through five years.

Decisions regarding the medical management of HeartMate 3 patients should be done by clinicians after fully considering potential risks and benefits for each individual.

Indications and Important Safety Information
For U.S. important safety information for the Abbott HeartMate 3, visit:HeartMate 3 LVAD Indications, Safety and Warnings | Abbott (cardiovascular.abbott).

For U.S. important safety information for the CardioMEMS HF System, visit:Pulmonary Pressure Monitors | Abbott (cardiovascular.abbott).

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 114,000 colleagues serve people in more than 160 countries.

Connect with us at www.abbott.com, on LinkedIn at www.linkedin.com/company/abbott-/, on Facebook at www.facebook.com/Abbott and on Twitter @AbbottNews.

1. Bozkurt, et. al. Heart Failure Epidemiology and Outcomes Statistics: A Report of the Heart Failure Society of America. J Card Fail. 2023; 29(10): 1412–1451.
2. Hashim, et al. Clinical Characteristics and Outcomes of Intravenous Inotropic Therapy in Advanced Heart Failure. Circ Heart Fail. 2015 Sep;8(5):880-6.

SOURCE Abbott

For further information: Abbott Media: Cole Heath, (651) 421-3655; Abbott Financial: Michael Comilla (224) 668-1872

Additional assets available online: Photos