Abbott Initiates Trial To Evaluate Improved Survival And Outcomes With The CardioMEMS Monitor

- THE CARDIOMEMS™ HF SYSTEM IS THE FIRST AND ONLY FDA-APPROVED HEART FAILURE MONITOR PROVEN TO SIGNIFICANTLY REDUCE HEART FAILURE HOSPITAL ADMISSIONS AND IMPROVE QUALITY OF LIFE

- NEW STUDY WILL EVALUATE WHETHER TREATMENT WITH THE CARDIOMEMS MONITOR IMPROVES SURVIVAL AND OUTCOMES FOR MORE PEOPLE

- GUIDE-HF IS THE LARGEST HEART FAILURE MEDICAL DEVICE TRIAL IN THE U.S.

ABBOTT PARK, Ill., March 29, 2018 /PRNewswire/ -- Abbott (NYSE: ABT) announced today the company has initiated the landmark GUIDE-HF clinical trial using the CardioMEMS™ HF System. The GUIDE-HF trial will study whether the CardioMEMS device can improve survival and quality of life for people living with New York Heart Association (NYHA) Class II – IV heart failure. The CardioMEMS HF System has already been proven, when managed by a physician, to significantly reduce heart failure hospital admissions and improve the quality of life for people living with NYHA Class III heart failure. Doctors use the NYHA classification system to classify heart failure according to the severity of a person's symptoms.

"Monitoring pulmonary artery pressure with Abbott's CardioMEMS device has already been shown to offer improvements in patient care. We now want to build a stronger body of clinical evidence, with GUIDE-HF, that establishes its role in improving patient survival," said JoAnn Lindenfeld, M.D., primary investigator for the GUIDE-HF trial and director of advanced heart failure at Vanderbilt University Medical Center in Nashville.

The prospective trial will enroll 3,600 patients at 140 hospitals acrossNorth America with stage C, New York Heart Association (NYHA) Class II-IV heart failure with either elevated brain-type natriuretic peptide (BNP) levels or prior heart failure hospitalizations in the past 12 months. More information on the trial is available at clinicaltrials.gov.

"Data suggests that proactively managing people living with heart failure may change the course of the disease's progression," said Philip B. Adamson, M.D., divisional vice president and medical director ofAbbott's Heart Failure business. "The CardioMEMS HF System is the first-of-its-kind approach to redefine heart failure management. The GUIDE-HF study sets out to make this technology available to an expanded group of people who could benefit from it."

First implants for the trial occurred recently at:

- Providence Hospital, Southfield, Michigan by Drs. Marcel Zughaib, and Herman Kado
- Sanford Medical Center, Sioux Falls, South Dakota by Dr. Orvar Jonsson
- Austin Heart, Austin, Texas by Dr. Kunjan Bhatt

The GUIDE-HF trial is designed to build on the clinical experience gained from theCHAMPION trial and aims to provide additional clinical evidence to further expand coverage for this first-of-its-kind technology.

About Heart Failure and the CardioMEMS™ HF System
Despite medical advances, hospitalization for heart failure is a worsening epidemic. More than 5.7 million people suffer from heart failure in the U.S. and approximately 915,000 additional people are diagnosed with the disease each year. The American Heart Association (AHA) predicts there will be more than 8 million heart failure patients in the U.S. by 2030, with an associated increase to three million hospitalizations yearly.

For people living with heart failure, changes in the pressure of blood through the pulmonary artery can indicate worsening heart failure—even before symptoms such as shortness of breath or weight gain are reported. Abbott's CardioMEMS HF System redefined this traditional approach to care by allowing physicians to remotely monitor pressure changes before the patient's symptoms progress. This personalized approach allows physicians to more proactively manage a patient's care while reducing the likelihood of hospitalization.

The CardioMEMS HF System features a small pressure-sensing device, no larger than the size of a small paperclip, that is implanted through a minimally invasive procedure, directly into the patient's pulmonary artery. While at home, patients lay on a special pillow to wirelessly take a pressure reading. Data from the sensor is collected through radio frequency to the pillow's antenna and then is sent wirelessly to the patient's doctor. This information can then be used by physicians to proactively adjust medications and treatment plans, if needed.

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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