GUIDE-HF Study Data Show Abbott's CardioMEMS™ Device Can Improve Care For More Patients With Heart Failure

- The GUIDE-HF study examined the potential impact of Abbott's CardioMEMS™ HF System, a small implantable pulmonary pressure sensor, in an expanded patient population not currently approved for the device

- Data from the GUIDE-HF trial suggests CardioMEMS can improve care for more types of patients battling heart failure and reduce hospitalizations, especially for patients suffering from earlier stages of the disease

ABBOTT PARK, Ill., Aug. 27, 2021 /PRNewswire/ -- Abbott (NYSE: ABT) today announced results of the landmark GUIDE-HF clinical trial, a 1,000 patient randomized study designed to assess the benefits of the CardioMEMS™ HF System in people living with NYHA Class II, III and IV heart failure. Data adjusted for the impact of COVID-19 show a strong reduction in a composite endpoint of heart failure hospitalizations, emergency visits and death in a broad range of patients, suggesting new benefits from the CardioMEMS device.

CardioMEMS is currently approved for use in NYHA Class III patients with a prior heart failure hospitalization within the last year. The GUIDE-HF study examined an expanded patient population, including patients with NYHA Class II and Class IV heart failure, to evaluate the device in patients in earlier or later-stage disease progression.

GUIDE-HF is one of many large trials conducted amid the COVID-19 pandemic, when healthcare systems experienced significant disruption. Heart failure patients are at a heightened risk of COVID-19 and – as a result – experienced changes to their care management and hospitalization during the pandemic. An analysis of the full one-year data set, of which 28% of the follow-up data was collected during COVID-19, showed CardioMEMS-guided patients had a lower composite endpoint rate of total heart failure events and death compared to the study's control group, which was not statistically significant. In an analysis of data adjusted for the impact of COVID-19 (captured prior to March 13, 2020 – the date the U.S. national emergency was declared), CardioMEMS demonstrated a significant 19% reduction in the study's composite endpoint and a 28% reduction in heart failure hospitalizations.

The results of GUIDE-HF were presented at the ESC Congress 2021 (organized by the European Society of Cardiology) and simultaneously published in *The Lancet.* Based on the strength of the GUIDE-HF data, Abbott has filed a Premarket Approval (PMA) supplement with the U.S. Food and Drug Administration (FDA) for consideration of an expanded indication for the CardioMEMS device.

The CardioMEMS HF System includes a small sensor the size of a paperclip that, once placed in the pulmonary artery during a minimally invasive procedure, monitors for pressure changes that indicate worsening heart failure even before patients feel symptoms. The CardioMEMS sensor connects to a system that remotely provides daily pressure readings to a patient's clinical team, allowing physicians to make therapy changes to combat worsening heart failure.

"The two most important strategies in treating heart failure are helping doctors stay ahead of the condition as it progresses and keeping people stable and out of the hospital and emergency room. The GUIDE-HF trial shows that Abbott's CardioMEMS device has a role in both," said Philip B. Adamson, M.D., chief medical officer of Abbott's heart failure business. "This tiny cardiac sensor, coupled with the increased improvements in informed telemedicine, can have a tremendous impact on helping people at all stages of heart failure live their healthiest lives."

GUIDE-HF Data Overview
Though not designed to assess the benefits of CardioMEMS in specific patient sub-groups, when adjusted for the impact of COVID-19, the GUIDE-HF study suggests potential benefits of the device in new groups of patients, including:

- **Patients in earlier stages of heart disease.** GUIDE-HF data suggests better outcomes in Class II patients when their therapy is guided by pulmonary pressure monitoring, with a 34% reduction in heart failure hospitalizations, emergency visits and death.
- **Specific patient groups.** GUIDE-HF also demonstrated a relative risk reduction for both women (33%) and African American patients (41%), two patient segments disproportionately impacted by effects of heart failure.
- **Patients at risk of potential hospitalization.** GUIDE-HF showed a 25% reduction in hospitalization or emergency department visits in patients without a prior heart failure hospitalization but who undergo blood tests that show elevated levels of a biomarker known as B-type Natriuretic Peptide (BNP), which indicates worsening heart failure.

"Clinicians have seen firsthand the importance of CardioMEMS in helping them proactively manage heart failure to keep patients out of the hospital, and the GUIDE-HF trial showed the device provides benefits for more patients than ever before," 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, Tenn. "Even with the disruptions that we saw as a result of the COVID-19 pandemic, this trial was still able to show significant reductions in heart failure hospitalizations and reduced emergency visits with pulmonary pressure sensor monitoring."

About the GUIDE-HF Study
Prior clinical and real-world evidence, including the landmark CHAMPION study, has shown substantial benefits of CardioMEMS, including reduced heart failure hospitalization, positive economic impact and reduction in pulmonary artery pressures – which physicians use to assess their patients' heart failure. GUIDE-HF built upon these prior studies by expanding

the patient population (Class II – IV and patients with elevated BNP or NT-proBNP levels), while also broadening the primary endpoint to include hospitalization, visits to emergency departments or outpatient urgent care centers and death.

The GUIDE-HF study included a randomized arm of 1,000 patients and a single arm of up to an additional 2,600 patients that is currently enrolling for a total of 3,600 patients across 118 centers in North America. All patients received a CardioMEMS device, but therapy for patients in the control arm was not guided by the device.

About the GUIDE-HF Study's COVID-19 Sensitivity Analysis
The COVID-19 pandemic had a significant impact on clinical trials, research procedures, patient behavior and hospitalizations. To reflect the point in time where patient behaviors and research procedures may have changed or potentially impacted the GUIDE-HF trial, Abbott received FDA approval in August 2020 to proactively add a COVID-19 sensitivity analysis to the study's statistical analysis plan. The analysis is designed to assess all data captured prior to March 13, 2020, when 1,000 patients had been enrolled, implanted and randomized, and 72% of the study's patient follow-up had been completed.

About CardioMEMS
CardioMEMS is currently only approved for NYHA Class III patients with a prior heart failure hospitalization within the last year. CardioMEMS is currently under investigation to treat patients outside of the existing approved indication in the U.S.

For U.S. important safety information for the CardioMEMS HF System, visit : https://www.cardiovascular.abbott/us/en/patients/treatments-therapies/pulmonary-artery-pressure-monitoring-for-heart-failure/important-safety-information.html

About Abbott:
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For further information: Abbott Media: Shelley Lange, (612) 346-3514; Abbott Financial: Mike Comilla, (224) 668-1872

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