Late-Breaking Data Show Breadth Of Abbott's Minimally Invasive Structural Heart Technologies

- Five late-breaking presentations at TCT 2022 highlight the impact of Abbott's structural heart devices to repair or replace heart valves and close openings in the heart
- New data reinforce the safety and effectiveness of MitraClip™ for treating mitral regurgitation
- Results also demonstrate the benefits of Abbott's TriClip™ for tricuspid regurgitation, Amulet™ for stroke reduction in patients with atrial fibrillation and Portico™ for aortic stenosis

ABBOTT PARK, Ill., Sept. 17, 2022 /PRNewswire/ -- Abbott (NYSE: ABT) today announced data from five late-breaking presentations showing the benefits of its minimally invasive devices in treating people with a range of structural heart diseases. Data include findings that reinforce the value of MitraClip™, the world's first and leading transcatheter edge-to-edge repair (TEER) device, to treat leaky valves in people with mitral regurgitation (MR).

The new data around Abbott's structural heart therapies were presented at the 34th Transcatheter Cardiovascular Therapeutics (TCT) annual scientific symposium of the Cardiovascular Research Foundation in Boston (September 16-19, 2022). Results were also presented on TriClip™, the first therapy designed specifically for tricuspid heart valve repair; the Amplatzer™ Amulet™ Left Atrial Appendage Occluder, a minimally invasive option offering the most complete closure of the left atrial appendage (LAA) to reduce risk of stroke; and Portico™, a self-expanding transcatheter aortic valve implantation (TAVI) system.

Structural heart diseases such as valve disease or openings in the heart that require closure can impair how the heart moves blood through the body. New minimally invasive technology has changed how physicians approach patient care and limits the need for more complex or risky surgery.

MitraClip EXPAND G4 Post-Approval Study
Data presented from the prospective, multi-center, global real-world EXPAND G4 study support the safety and effectiveness of the MitraClip G4 system for treating MR. The study represents the largest report of 30-day core lab-assessed outcomes, which included more than 1,000 patients. The data confirm that MitraClip offers high success rates in terms of MR reduction, improvements in quality of life and low adverse event rates.

Key findings through 30 days include:

- Significant MR reduction to mild or less (≤ grade 1+ on a four-point scale) is achieved in 91% of patients, with lowest reported adverse event rates to date (1.3% all-cause mortality at 30 days)
- Clinical improvements including 83% of patients achieving New York Heart Association (NYHA) Functional Class I/II (a classification of functional limitations resulting from cardiac disease, with Class I/II meaning slight or no limitation of physical activity), an improvement of 52% from baseline of 31%; and an 18-point improvement in the Kansas City Cardiomyopathy Questionnaire (KCCQ) score (a self-assessment of social abilities, symptoms and quality of life), a 35% improvement from baseline score
- Multiple clip sizes enable tailoring the therapy to patients' mitral valve anatomy and expand the spectrum of TEER-suitable patients

"MitraClip therapy has fundamentally changed the way doctors treat mitral regurgitation, provides a valuable therapy option that does not require open-heart surgery, and goes beyond simply managing symptoms with medications," said Jason Rogers, M.D., professor of cardiovascular medicine and director of interventional cardiology and structural heart training programs at the University of California, Davis Medical Center. "These late-breaking data demonstrate and strengthen the evidence that Abbott's MitraClip system consistently reduces MR in a broad range of patients, while restoring proper function of the mitral valve and improving patients' quality of life."

The MitraClip system has been commercially available in the U.S. since 2013 and in Europe since 2008. With more than 150,000 patients treated worldwide, MitraClip is approved in more than 75 countries, spanning regions in Asia, Africa, Europe, the Americas and Australia.

"These results add to what's been proven through nearly two decades of clinical experience in transcatheter mitral repair – MitraClip provides long-term, significant mitral regurgitation reduction that changes and saves lives," said Michael Dale, senior vice president of Abbott's structural heart business. "Abbott was the first to offer a transcatheter mitral valve repair device that provides a minimally invasive treatment option for patients with MR who would otherwise go untreated, and we remain committed to addressing the unmet needs of people with structural heart conditions."

First Results from the TriClip TRILUMINATE Pivotal Trial
TRILUMINATE Pivotal is the first randomized, controlled clinical trial evaluating the safety and effectiveness of TEER with TriClip in 700 patients with severe TR in the U.S., Canada and Europe. The data from the roll-in cohort through 30 days show:

- High implant success rate (99%)
- At least a one-grade TR reduction in 91% of patients, with moderate or less residual TR achieved in 74%
- Patients achieving around a 17-point improvement in the KCCQ score, a 30% improvement from baseline score, which demonstrates a substantial improvement in their quality of life

Three-Year Outcomes from the Amulet IDE Study

The Amplatzer Amulet LAA Occluder with dual-seal technology (consisting of a lobe or piece to fill the cavity of the LAA and a disc to close off the opening into the LAA) is the first and only minimally invasive treatment option to offer immediate and complete dual-sealing closure of the LAA, reducing the risk of stroke and eliminating the need for blood-thinning medication. The prospective, international, multi-center Amulet IDE trial is the largest randomized LAA occlusion study to date consisting of more than 1,800 patients, and three-year outcomes demonstrate the safety and effectiveness of Amulet, with data showing:

- Device-related factors (device-related thrombosis or peri-device leak) more frequently preceded strokes in patients with Boston Scientific's Watchman‡ than those with Amulet
- Both cardiovascular and all-cause death trended higher in the Watchman device than the Amulet device

PREDICT-LAA Trial (Amulet)
Data were also presented from the PREDICT-LAA prospective, multi-center, randomized controlled trial that studied if the use of cardiac computed tomography-based computational models (high-resolution scans of patients' hearts generated by FEops HEARTguide‡) help in the planning of Amplatzer Amulet procedures. Key findings at three months include:

- Improved procedural efficiency and safety outcomes with the Amplatzer Amulet LAA Occluder were achieved when planned with HEARTguide

Portico CONFIDENCE Registry
The CONFIDENCE Registry is an international, prospective, real-world study evaluating the safety and effectiveness of the Portico TAVI valve using the first-generation Portico delivery system in 501 patients and the second-generation FlexNav™ delivery system in 500 patients. Late-breaking data on valve hemodynamics (blood flow) at 30 days and one-year survival following implantation of the Portico TAVI device will be presented at TCT on Sunday, Sept. 18

For U.S. important safety information on MitraClip, visit http://abbo.tt/MitraClipG4ISI.

For U.S. important safety information on Amulet, visit https://abbo.tt/AmuletISI.

For U.S. important safety information on Portico, visit https://abbo.tt/PorticoISI.

The TriClip Transcatheter Tricuspid Valve Repair System is an investigational device only in the U.S.

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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