New Late-Breaking Data Highlight Impact Of Abbott's Minimally Invasive Structural Heart Therapies

- New data reinforce Abbott's leadership in minimally invasive treatment options for mitral and tricuspid repair and replacement therapies

- Eleven late-breaking presentations at the PCR e-Course showcase impact of Abbott's innovative structural heart portfolio on patient outcomes and quality of life in real-world and clinical settings

ABBOTT PARK, Ill., June 25, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) today announced late-breaking data on a number of its life-changing products to treat people with structural heart diseases. The data included findings on the MitraClip™ system for transcatheter mitral valve repair and data on two first-in-the-world devices approved in the EU: the TriClip™ system* for transcatheter tricuspid valve repair and the Tendyne™ transcatheter mitral valve implantation system* for people needing a replacement mitral valve.

Clinical and real-world evidence show that transcatheter devices can dramatically change the treatment approaches for complex cardiac conditions. The body of data spanning these technologies show continued positive outcomes for less invasive transcatheter therapies and emphasize Abbott's commitment to advancing new treatment options for people with mitral regurgitation (MR) and tricuspid regurgitation (TR).

The new late-breaking data on Abbott's transcatheter structural heart therapies will be presented as part of a virtual three-day PCR e-Course held by the European Association of Percutaneous Cardiovascular Interventions (EAPCI),June 25-27.

Treating Mitral Regurgitation with Repair and Replacement
One of the most common types of heart valve diseases, MR affects nearly one in 10 people over the age of 75, and is a condition in which the flaps, or leaflets, of the mitral valve do not close properly, allowing blood to flow backward into the heart. The disease can cause debilitating and sometimes fatal symptoms, yet people with MR are often not eligible for the standard-of-care open-heart surgery because of their age, frailty, comorbidities or other complicating factors. New data presented at the PCR e-Course demonstrate:

- **MitraClip is confirmed to have leading safety and effectiveness in the largest dataset yet**Real-world outcomes from four separate analyses of the global EXPAND study showed significant MR reduction (to ≤1+ in 87.1% of patients at 30 days for primary MR and 90.1% in patients with secondary MR) was consistently achieved with Abbott's MitraClip NTR/XTR systems in patients with either primary or secondary MR. The EXPAND study is the largest contemporary investigation of real-world MitraClip outcomes studying more than 1,000 patients who received Abbott's third-generation device, MitraClip NTR/XTR, at 57 sites worldwide.
- **Tendyne, the world's first transcatheter mitral valve replacement device, provides long-lasting severe MR symptom relief at two-year follow-up.** Clinical outcomes from an analysis of 100 patients with symptomatic, moderate-to-severe or severe MR treated in the EU Clinical Study of the Tendyne Mitral Valve System – a first-to-world minimally invasive mitral valve replacement device recently approved for use in the EU – demonstrated durability of MR elimination in 93.2% of patients and significant improvements in quality of life and functional capacity at two years. This study data supports the valve as a safe treatment option that provides symptom relief and improved quality of life for people with symptomatic MR who are not eligible for open-heart surgery or transcatheter mitral valve repair.

"Historically, people who were ineligible for standard-of-care surgeries to treat their mitral or tricuspid regurgitation were limited to symptom management, which does not address the underlying condition," said Paul Sorajja, M.D., the Roger L. and Lynn C. Headrick Family Chair of the Valve Science Center for the Minneapolis Heart Institute Foundation and director of the Center for Valve and Structural Heart Disease for the Minneapolis Heart Institute at Abbott Northwestern Hospital. "These devices treat extremely complex valve diseases that are debilitating and progress to very serious conditions when left untreated. The late-breaking data show significant and consistent reduction in regurgitation, allowing the heart valve to function as it is intended."

Driving New Treatment Options for Tricuspid Regurgitation with TriClip
Tricuspid valve regurgitation occurs when the valve between the two right chambers (right ventricle and right atrium) of the heart don't close, allowing blood to flow backwards into the right atrium of the heart. For people with TR, surgery has traditionally been the only treatment option available but is rarely performed due to its complexity and risks.

Building on the proven success of MitraClip's clip-based technology to combat regurgitation, data from the TRILUMINATE CE Mark study evaluating TriClip, the first minimally invasive, clip-based tricuspid valve repair device approved in the EU, shows the impact of the therapy for patients suffering from TR in 85 patients across 21 sites in Europe and the United States.

New late-breaking trial data with longer term follow-up (one-year) showed:

- **Sustained TR Reduction with TriClip.** TRILUMINATE data showed strong TR reduction in 87.1% of patients who received Abbott's TriClip and a low all-cause mortality rate of 7.1% at one year.
- **Positive impact of right ventricular function.** The study also showed sustained improvements in right heart function demonstrating the benefits of tricuspid valve treatment.
- **The safety and durability of TriClip performance.** By meeting the TRILUMINATE CE Mark study's primary safety and efficacy endpoints, the TRILUMINATE research team concluded that TriClip is a safe and durable treatment option for high-risk patients with symptomatic moderate or greater TR.

New Data for Patients with Severe Aortic Stenosis and Atrial Fibrillation
Additional U.S. IDE data from Abbott's structural heart portfolio were also presented during the PCR e-Course, including findings on two of its devices* commercially available in the EU: Amplatzer™ Amulet Left Atrial Appendage (LAA) Occluder* – a stroke prevention product for people with atrial fibrillation – and Portico™ transcatheter aortic valve replacement (TAVR).

- **Amplatzer Amulet has a consistent and high implant success rate.** First analysis of one-year clinical outcomes from the roll-in cohort of the Amulet IDE trial demonstrated a high implant success rate of 99.0% and a low rate of procedural complications at 3.5%.
- **Portico with FlexNav™ demonstrates continued safety and performance.** Findings from the three studies of Abbott's TAVR support Portico as a durable treatment option with excellent hemodynamic results and long-term performance for patients suffering from severe aortic stenosis who are at high risk for open-heart surgery, while Abbott's new FlexNav™ delivery system was shown to provide an enhanced safety profile for the Portico device.

These positive findings on Amplatzer and Portico presented as late-breaking clinical trials during the PCR e-Course add to the mitral and tricuspid late-breaking data and demonstrate the breadth of Abbott's structural heart portfolio.

"At Abbott, we are advancing science and innovative technology to ensure people living with structural heart diseases have safe and effective treatment options," said Michael Dale, senior vice president of Abbott's structural heart business. "The data presented during this year's PCR underscore our unwavering commitment to solve the health challenges of those managing debilitating heart conditions."

For U.S. important safety information on MitraClip, visit: https://www.structuralheartsolutions.com/us/mitraclip-isi.

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 107,000 colleagues serve people in more than 160 countries.

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*These products are available commercially in the EU and are in clinical trials in the United States.

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

The Tendyne Transcatheter Mitral Valve Implantation System is an investigational device only in the U.S.

The Amplatzer Amulet LAA Occluder is an investigational device only in the U.S.

The Portico Transcatheter Aortic Valve Replacement System is an investigational device only in the U.S.

The FlexNav Delivery system for Portico is an investigational device only in the U.S.

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