Late-Breaking Data Showcase The Benefits Of Abbott's Minimally Invasive Devices For People With Leaky Heart Valves

- New data presented at Transcatheter Cardiovascular Therapeutics (TCT) 2023 from the TRILUMINATE™ pivotal trial confirm safety, effectiveness and improvements in quality of life when treating tricuspid regurgitation (a leaky valve) with TriClip™, an investigational device in the U.S.
- One-year outcomes from the EXPAND G4 study, simultaneously published in *JACC: Cardiovascular Interventions,* reinforce durable safety and effectiveness of MitraClip™ with significant mitral regurgitation reduction

ABBOTT PARK, Ill., Oct. 24, 2023 /PRNewswire/ -- Abbott (NYSE: ABT) today announced data from late-breaking presentations showing the impact of its minimally invasive heart devices in treating mitral and tricuspid valve disease. Data include findings from the TRILUMINATE™ pivotal trial that reinforce the safety and effectiveness of the TriClip™ transcatheter edge-to-edge repair (TEER) system for patients with symptomatic, severe tricuspid regurgitation (TR) despite optimal medical therapy.

The company also presented late-breaking data from the MitraClip™ EXPAND G4 real-world registry that highlights the device's benefits across a broad group of patients with mitral regurgitation (MR).

Leaky valves in people with MR and TR can reduce the amount of blood being pumped through the body and make the heart work harder than it should. As a result, MR and TR can lead to other cardiovascular issues as well as severely limit a person's quality of life. While historically surgery was often necessary to combat MR and TR, Abbott's minimally invasive portfolio of structural heart devices has allowed more people around the world to be effectively treated without the risk of surgical complications.

The following studies using products from Abbott's industry-leading structural heart portfolio were presented at the 35th Transcatheter Cardiovascular Therapeutics (TCT) annual scientific symposium of the Cardiovascular Research Foundation in San Francisco (October 23-26, 2023).

TriClip: New TRILUMINATE Pivotal Trial Data
The TRILUMINATE pivotal trial is the world's first randomized, controlled clinical study evaluating the safety and effectiveness of transcatheter repair with the TriClip system compared to medical therapy in people with severe TR. Outcomes to date for all randomized patients (N=572) and those enrolled in the concurrent single-arm group (patients with more complex tricuspid valve anatomy) were presented for the first time at TCT and illustrated the device's safety, effectiveness and benefits.

Key findings from the TRILUMINATE pivotal trial through one year include:

- Consistent with and reinforcing the findings in the primary randomized population (N=350, presented at ACC 2023), TriClip therapy demonstrated significant improvements in quality of life as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) score (a self-assessment of social abilities, symptoms and quality of life) for the full randomized group, along with an excellent safety profile.
- The single-arm group with more complex anatomies and advanced disease met its primary endpoint. The data demonstrated that TriClip was safe, with 81% of patients achieving TR reduction to moderate or less and reporting a similar degree of KCCQ improvement to the randomized population.

"The updated TRILUMINATE pivotal results confirm what has previously been shown – that TriClip is safe and effective for patients with severe tricuspid regurgitation," said David Adams, M.D., chairman of the department of cardiovascular surgery at the Icahn School of Medicine at Mount Sinai and cardiac surgeon-in-chief of the Mount Sinai Health System, who served as co-primary investigator of the trial. "With the addition of the single-arm data that include people with more complex tricuspid anatomies, the takeaway is that TriClip is reducing TR effectively and patients are subsequently experiencing improvement in their quality of life."

MitraClip: One-Year Results From the EXPAND G4 Study
The EXPAND G4 study is a prospective, multi-center, global, real-world study of more than 1,100 patients that reinforces the safety and effectiveness of the MitraClip G4 system in people with a broad range of anatomies. One-year results were simultaneously published in *JACC: Cardiovascular Interventions*.

Key findings from the EXPAND G4 study at one year include:

- The highest reported MR reduction in a mitral TEER study to date, sustained through one year, with MR reduction to mild or less (≤ grade 1+ on a five-point scale) achieved in 93% of patients, and trace or less MR achieved in 44% of patients.
- Significant clinical improvements, including 82% of patients achieving New York Heart Association (NYHA) Functional Class I/II (meaning they reached a point of slight or no limitation of physical activity), an improvement from 36% at baseline; and a 19-point improvement in KCCQ score.
- MitraClip showed the lowest rates of all-cause mortality (12%) and hospitalization for heart failure (17%) in a global, real-world mitral TEER study.

"These late-breaking data at TCT offer further evidence that our innovative, minimally-invasive heart devices are having a positive impact on the lives and well-being of those with structural heart disease," said Michael Dale, senior vice president of

Abbott's structural heart business. "For more than two decades, Abbott has continued to evolve and expand its minimally invasive treatment options for mitral and tricuspid regurgitation. Our portfolio of technologies to restore health and improve the quality of life of patients with leaky valves represents new standards of care and an example of our commitment to leadership in the treatment of structural heart disease."

For U.S. important safety information on MitraClip, visit https://abbo.tt/MitraClipISI.

TriClip is approved for use in more than 50 countries, including in Europe and Canada, and is an investigational device 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 115,000 colleagues serve people in more than 160 countries.

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