New Data Show Superiority Of Abbott's TriClip™ Device Compared To Medical Therapy For Tricuspid Regurgitation

- Late-breaking data presented at American College of Cardiology Scientific Sessions (ACC.23) and simultaneously published in *The New England Journal of Medicine* demonstrate TriClip was superior to medical therapy with significant improvements in quality of life and tricuspid regurgitation (TR)
- Findings show TriClip, an investigational device in the U.S. to treat a leaky tricuspid valve, demonstrated safety and met the primary endpoint

ABBOTT PARK, Ill., March 4, 2023 /PRNewswire/ -- Abbott (NYSE: ABT) today announced late-breaking data for the TriClip™ transcatheter edge-to-edge repair (TEER) system, a first-of-its-kind minimally invasive device designed specifically for tricuspid heart valve repair. The TRILUMINATE™ Pivotal study evaluates the superiority of TriClip compared to medical therapy in treating patients with severe, symptomatic tricuspid regurgitation (TR) who are at intermediate or greater risk for open-heart surgery.

The results were presented at the American College of Cardiology's 72nd Annual Scientific Session together with World Congress of Cardiology (ACC.23/WCC) held in New Orleans (March 4-6, 2023). These data were simultaneously published in *The New England Journal of Medicine*.

Key Findings From the TRILUMINATE Pivotal Study
The trial met its composite primary endpoint demonstrating superiority of the TriClip system compared to the control group (win ratio 1.48, p=0.02), primarily driven by improvement in quality of life. Mortality or tricuspid valve surgery and heart failure hospitalizations did not appear different between the groups at one year. Other positive findings include:

- Significant reduction in TR grade. Significant reduction in TR to moderate or less (grade ≤ 2) was achieved in 87% of patients with the device at 30 days vs. 4.8% in the control group, with TR reduction sustained and durable at one year.
- Significant improvement in quality of life. 50% of patients who received the device achieved at least a 15-point improvement in the Kansas City Cardiomyopathy Questionnaire (KCCQ) score (a self-assessment of social abilities, symptoms and quality of life) at one year vs. 26% in the control group.
- A strong safety profile. At 30 days, only 1.7% of patients who received the device experienced major adverse events, with no urgent surgery or endocarditis. There were no occurrences of device embolization or device thrombus.

"These TRILUMINATE Pivotal trial results are promising because there have historically been very few treatment options for tricuspid regurgitation, and patients with this condition are often not eligible for open-heart surgery due to multiple co-morbidities or other factors," 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. "The trial data and real-world use in Europe from the bRIGHT post-approval study show TriClip's ability to safely and effectively repair the tricuspid valve in patients and improve their quality of life."

"These TRILUMINATE Pivotal data show TriClip is the first minimally invasive device therapy for the treatment of tricuspid regurgitation to provide durable improvements in TR severity and quality of life that go beyond taking medication to manage symptoms," said Michael Dale, senior vice president of Abbott's structural heart business. "When left unaddressed, TR can be debilitating and life-threatening. By repairing the damage caused by structural heart disease, TriClip G4 and our latest technological innovations are helping people reclaim their lives so they can get back to doing what they love."

Abbott will also be presenting at ACC late-breaking five-year results from its landmark COAPT™ trial of the MitraClip™ TEER device for functional mitral regurgitation in heart failure.

About the Abbott TRILUMINATE Pivotal Trial
The TRILUMINATE Pivotal trial is the first randomized, controlled clinical study to evaluate the safety and effectiveness of transcatheter repair with the TriClip system compared to medical therapy in people with severe TR.

The primary endpoint was a composite of all-cause mortality or tricuspid valve surgery, heart failure hospitalizations, and quality-of-life improvement measured by the KCCQ score.

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

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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For further information: Abbott Media: Cynthia Kong, (669) 400-6879; Abbott Financial: Mike Comilla, (224) 668-1872

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