New Late-Breaking Data Reinforce Benefits Of Abbott's TriClip™ For People With Leaky Tricuspid Heart Valve

- TRILUMINATE™ Pivotal data presented at the American College of Cardiology's Annual Scientific Session (ACC.25) and simultaneously published in *Circulation* show the Abbott TriClip system reduces heart failure hospitalizations
- The latest results highlight significant improvements in tricuspid regurgitation and quality of life through two years

ABBOTT PARK, Ill., March 31, 2025 /PRNewswire/ -- Abbott (NYSE: ABT) today announced late-breaking data from its TRILUMINATE™ Pivotal trial that show the TriClip™ transcatheter edge-to-edge repair (TEER) system to treat tricuspid regurgitation (TR), or a leaky heart valve, offers substantial and sustained improvements in the severity of TR after two years. The results also demonstrate the TriClip device significantly reduced the rate of hospitalizations due to heart failure compared to medical therapy, while offering long-term quality-of-life benefits for patients.

TR can reduce the amount of blood being pumped through the body and force the heart to work harder than it should, causing debilitating symptoms such as fatigue and shortness of breath. When left untreated, TR can lead to atrial fibrillation, heart failure and, ultimately, death. For those who are not good candidates for surgery and continue to have symptoms or persistent TR despite treatment with medical therapy, TriClip represents a needed option that can improve a person's quality-of-life and keep them out of the hospital.

The data were presented at the American College of Cardiology's Annual Scientific Session (ACC.25) held in Chicago (March 29-31, 2025) and simultaneously published in *Circulation*.

Sustained Benefits for Patients With Severe Leaky Heart Valve
After two years, the TRILUMINATE Pivotal study found TriClip continued to demonstrate superiority compared to medical therapy while meeting the secondary endpoints of recurrent heart failure hospitalizations (HFH) and freedom from all-cause mortality, tricuspid valve surgery and tricuspid valve intervention. After the first year of the trial, patients in the control group (medical therapy) were allowed to cross over to receive TriClip therapy, and more than half (142 of 241 eligible patients) received TriClip.

Additional positive two-year findings from the TRILUMINATE Pivotal trial include:

- **Significant reduction in HFH.** The rate of HFH was significantly lower in the treatment group compared to the control group (0.19 vs. 0.26 events/patient-year, p=0.02). Also, control patients who switched to TriClip treatment had a drop in HFH after receiving the device (0.5 vs. 0.35 events/patient-year).
- **Significant, sustained reduction in TR grade.** Significant reduction in TR to moderate or less (grade ≤ 2) was achieved in 84% of patients with the device vs. 21% of patients in the control group. Similar improvements were seen in the control group patients who crossed over, with 81% of patients achieving moderate or less TR at 30 days after receiving TriClip compared to 3% prior to crossing over.
- **Significant, sustained improvement in quality of life.** Patients who received TriClip achieved more than a 15-point improvement on average in the Kansas City Cardiomyopathy Questionnaire (KCCQ) score (a self-assessment of social abilities, symptoms and quality of life) throughout follow-up. Patients in the crossover group achieved similar improvements in KCCQ score (+13 points on average) once implanted with TriClip.

"With the TRILUMINATE Pivotal two-year results, tricuspid transcatheter edge-to-edge repair with the TriClip device for severe, symptomatic tricuspid regurgitation reduced heart failure hospitalizations compared to the control group. Improvements in tricuspid regurgitation severity and quality of life were sustained through two years," said Saibal Kar, M.D., Los Robles Regional Medical Center in Thousand Oaks, California. "When we combine this with the consistent quality-of-life improvements people who receive the TriClip system experience, it's clear that the benefits for patients with TR are very meaningful and TriClip offers a safe, effective and sustainable way to repair the tricuspid valve."

"These new data reinforce the critical role TriClip plays in helping people with tricuspid regurgitation live the life they want while reducing the risk of hospitalization," said Sandra Lesenfants, senior vice president of Abbott's structural heart business. "Patients battling TR face serious challenges, including increased risk of heart failure, as a result of this debilitating condition. Unfortunately, many are not eligible for open-heart surgery and had limited treatment options prior to the approval of TriClip, a significant advancement that allows patients to reclaim their lives."

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 alone 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.

TriClip is approved for use in more than 50 countries, including in the U.S.,Europe and Canada.

For U.S. important safety information on TriClip, visit https://abbo.tt/TriClip_ISI.

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