Late-Breaking Data From Landmark COAPT™ Trial Show Long-Term Benefits Of Abbott's MitraClip™ Device

- New five-year data presented at American College of Cardiology Scientific Sessions (ACC.23) and simultaneously published in *The New England Journal of Medicine* reinforce the long-term safety and effectiveness of MitraClip for treating secondary mitral regurgitation (MR)
- Results show minimally invasive mitral valve repair in advanced heart failure patients reduces hospitalizations and deaths and provides durable reduction in the severity of MR
- Historically, advanced heart failure patients battling secondary MR (a leaky mitral valve caused by problems affecting other areas of the heart) have been challenging to treat as a result of limited therapy options

ABBOTT PARK, Ill., March 5, 2023 /PRNewswire/ -- Abbott (NYSE: ABT) today announced late-breaking data for MitraClip™, the leading therapy to treat leaky valves in people with mitral regurgitation (MR), that demonstrate long-term benefits of the device in patients battling heart failure. The five-year results from the landmark COAPT™ trial show MitraClip is safe and effective and can cut the rate of hospitalizations while improving survival for heart failure patients with severe secondary (or functional) MR, a condition which has historically been extremely challenging to treat.

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*.

Five-Year Results From the COAPT Trial
In the COAPT trial, symptomatic heart failure patients with severe secondary MR (a condition in which a leaky valve caused by problems affecting other areas of the heart allows blood to flow back through the mitral valve) were randomized to receive treatment with MitraClip plus guideline-directed medical therapy or guideline-directed medical therapy alone. The primary results of the COAPT trial through two years found MitraClip to be superior to guideline-directed medical therapy in patients with significant secondary MR.

Now, after five years of patient follow-up, data from the COAPT trial demonstrated even more substantial benefits for patients, including that MitraClip:

- Significantly reduced the risk of annualized hospitalizations by nearly half (33% per year vs. 57% in the control group)
- Reduced the risk of death by almost 30% (57% vs. 67% in the control group)
- Achieved durable MR reduction, with 95% of patients experiencing reduced MR from moderate-to-severe or severe (grade ≥ 3+ on a four-point scale) to mild or moderate (grade ≤ 2+)

"Secondary mitral regurgitation is difficult to diagnose and manage, and is often associated with a poor prognosis," said Gregg W. Stone, M.D., director of academic affairs for the Mount Sinai Health System and professor of medicine (cardiology) and population health science and policy at the Icahn Mount Sinai, who served as co-principal investigator of the COAPT trial. "These five-year COAPT results further confirm that MitraClip is safe and effective at treating secondary MR in advanced heart failure patients, durably reducing hospitalizations and helping patients live longer."

While primary MR is due to problems with the mitral valve itself, people with heart failure may develop secondary MR when the left chamber of the heart becomes enlarged, preventing the mitral leaflets from closing and allowing blood to flow backwards through the heart. Significant secondary MR can lead to reduced quality of life, recurrent hospitalizations and decreased survival. Prior to MitraClip, most heart failure patients with clinically significant secondary MR were treated with medication only. However, based on the strength of the primary results of the COAPT trial, in 2019 the FDA approved an expanded indication for MitraClip to treat secondary MR.

"With nearly two decades of clinical experience in transcatheter mitral repair, Abbott's MitraClip has paved the way for innovation in helping people with mitral regurgitation, providing an alternative to surgery for patients who often need treatment to survive," said Michael Dale, senior vice president of Abbott's structural heart business. "These results reinforce that MitraClip plays a critical role in not only improving the symptoms of people with this serious heart condition, but also getting them back to living their fullest lives."

Patients in the COAPT trial received the first-generation MitraClip, the world's first transcatheter edge-to-edge repair (TEER) device. Since the introduction of MitraClip, there have been advances in the device, with the fourth generation of the technology currently on the market, which can reduce MR further. More than 150,000 patients have been treated with MitraClip globally.

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

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