LATE-BREAKING DATA SHOWS ABBOTT'S MITRACLIP™ IS COST EFFECTIVE, INCREASES LIFE EXPECTANCY AND IMPROVES QUALITY OF LIFE

- New late-breaking data at TCT 2019 demonstrate that Abbott's MitraClip™ is cost-effective for heart failure patients with significant secondary mitral regurgitation compared to guideline-directed medical therapy alone

- Data analyses presented at TCT demonstrated that over the lifetime of a typical COAPT patient, MitraClip showed improvements in both projected life expectancy and quality of life, and that those benefits are sustained through three years

SAN FRANCISCO, Sept. 29, 2019 /PRNewswire/ -- Abbott (NYSE: ABT) today announced new analyses of the landmark COAPT™ Trial that show the company's MitraClip™ device is cost effective and is projected to increase both life-expectancy and quality of life compared to guideline-directed medical therapy (GDMT) alone in heart failure patients with secondary mitral regurgitation (MR), or a leaky mitral heart valve. The cost-effectiveness analysis also showed additional benefits of MitraClip, including decreased use of health resources after implantation.

The data were presented during the late-breaking clinical trial session at the 31st Transcatheter Cardiovascular Therapeutics (TCT) annual scientific symposium of the Cardiovascular Research Foundation in San Francisco (September 25 - 29) and simultaneously published in the journal *Circulation*.

In addition, a second late-breaking data presentation at TCT showed that over a longer-term follow-up period within the COAPT Trial, MitraClip continued to remain safe, with durable MR reduction, reduced hospitalization rates, and improved survival and quality of life compared to medical therapy alone.

In tandem, the two late-breaking data sets provide strong evidence of MitraClip's impact on treating secondary MR. Significant secondary MR has historically been difficult to manage, is associated with a poor prognosis,[1] and can lead to reduced quality of life, recurrent hospitalizations and decreased survival.[2,3]

"With longer-term follow-up we continue to see extended benefits from treatment with MitraClip in advanced heart failure patients with severe mitral regurgitation, and are encouraged by the latest findings demonstrating it is also a cost-effective treatment," said Gregg W. Stone, M.D., co-principal investigator of the COAPT Trial, Director of Academic Affairs for the Mount Sinai Heart Health System and Professor of Medicine and Population Health Sciences and Policy at the Icahn School of Medicine at Mount Sinai, New York.

"The pinnacle for all breakthrough therapies is to enhance patient longevity and quality of life in a cost-effective manner. These late-breaking data demonstrate that the MitraClip provides tremendous health benefits for select heart failure patients at a cost that is acceptable to the US health care system," said Stone.

The Importance of Societal & Economic Value
Cost effectiveness data are often used by many payers and health authorities around the world when making coverage and reimbursement decisions.

The COAPT Trial cost-effectiveness analysis demonstrated:

- Transcatheter mitral valve repair (TMVr) using MitraClip in patients with significant secondary MR was projected to increase life-expectancy by 1.13 years and quality-adjusted life-years by 0.82 years.
- TMVr using MitraClip in patients with significant secondary MR yielded an "Incremental Cost-Effectiveness Ratio" (ICER) of $55,600 per quality-adjusted life year vs GDMT. *(ICER is a commonly used health economic measure where the lower the ICER score, the more cost-effective the therapy. An ICER score of $55,600 implies that MitraClip provides a positive health economic value, with ICER scores lower than $100,000 generally considered as cost-effective therapy.)*

The health economic data from the COAPT Trial is the first time a pre-specified economic analysis was integrated into a pivotal randomized controlled trial that involved a mitral valve repair device.

Durable, Long-Term Results of MitraClip for Treating Secondary MR
Previously, data from the COAPT Trial had demonstrated the benefits of MitraClip for select heart failure patients with clinically significant secondary MR. Now, new three-year data provides important insights into the durability of the therapy over long-term follow-up.

Results show that, compared with guideline directed medical therapy , TMVR using MitraClip was:

- Safe, provided continued reduction in MR, reduced the rate of heart failure hospitalizations *(35.5% vs. 68.8%, HR [95% UCL] = 0.49 [0.63]; P<0.0001)*
- Improved survival *(all-cause mortality: 42.8% vs. 56.5%, HR [95% UCL]=0.64[0.82]; p=0.004)* at 36 months
- Provided durable improvements in quality of life at 24 months compared to medical therapy *(average*

improvement in Kansas City Cardiomyopathy Questionnaire Score: 7.8 vs. -12.1 points, p<0.001).

The three-year clinical results may further help inform a coverage review being conducted by the Centers for Medicare & Medicaid Services' (CMS) for an expanded National Coverage Determination of the procedure. CMS anticipates issuing a proposed decision memo in February 2020 and will issue a final decision in May 2020.

"Data from the COAPT Trial has consistently shown that treatment with MitraClip provides a great benefit for these heart failure patients," said Michael Dale, vice president of Abbott's structural heart business. "The strong data showcasing the societal and economic value of the therapy, combined with even longer-term durability data, provides additional support to put MitraClip in the hands of more physicians to improve the outcomes of their patients."

About the MitraClip System
MitraClip is a small, clip-based device has proven to repair primary and secondary MR without the need for open-heart surgery. The device is delivered to the heart through a small incision in the leg and works by clipping together a portion of the leaflets of the mitral valve to reduce the backflow of blood, which allows the heart to pump blood more efficiently.

The MitraClip system has been commercially available in the U.S. since 2013 and in Europe since 2008. With more than 15 years of clinical experience and more than 80,000 patients treated worldwide, the MitraClip system is the first transcatheter mitral valve therapy with proven safety and the only with proven survival and durable clinical outcomes.

MitraClip was approved in the U.S. in 2013 for primary MR patients. In March 2019, FDA approved MitraClip for secondary MR patients based on results from the COAPT Trial, which investigated MitraClip for treating secondary MR. A landmark trial, COAPT showed a 47% relative reduction in hospitalizations and a 38% relative reduction in mortality. Both primary and secondary MR patients may benefit from MitraClip therapy based on this expanded indication for MitraClip.

Abbott is the global leader in developing transcatheter mitral valve technologies as alternatives to open-heart surgery. Building upon its success with the MitraClip device and many years of mitral valve experience and clinical evidence, Abbott is also leading the way in novel, transcatheter devices by investing in the development and clinical study of new mitral valve replacement technologies.

For more information on MitraClip, visit: www.structuralheartsolutions.com.

For U.S. Important Safety Information about MitraClip, visit: https://www.structuralheartsolutions.com/us/mitraclip-isi.

About Abbott
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[1] Dwivedi A, Vainrib A, Saric M. Functional mitral regurgitation in patients with heart failure and depressed ejection fraction. Current Opinion in Cardiology. September 2016 - Volume 31 - Issue 5 - p 483–492.

[2] Sannino A, Smith II RL, Schiattarrella GG, et al. Survival and cardiovascular outcomes of patients with secondary mitral regurgitation: a meta-analysis of 53 studies. JAMA Cardiology 2017; 2:1130-39.

[3] Goliasch G, Bartko PE, Pavo N, et al. Refining the prognosis impact of functional mitral regurgitation in chronic heart failure. Eur Heart J 2018;39:39-46.

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