Abbott Receives Expanded Medicare Reimbursement For First-Of-Its-Kind MitraClip™ Device

- New national reimbursement enables access to transcatheter mitral valve repair procedures with MitraClip for people with secondary mitral regurgitation, significantly expanding the eligible patient population

ABBOTT PARK, Ill., Jan. 20, 2021 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Centers for Medicare & Medicaid Services (CMS) revised its National Coverage Determination (NCD) to expand coverage for transcatheter edge-to-edge repair (TEER), also referred to as transcatheter mitral valve repair (TMVr), to include patients with secondary (or functional) mitral regurgitation (MR) resulting from heart failure. The decision significantly increases the number of people eligible for insurance coverage for mitral valve repair with MitraClip, enabling broader access to the device. As the first and only TEER device approved by the U.S. Food and Drug Administration (FDA) and reimbursed by Medicare for primary mitral regurgitation, physicians have increasingly relied on the therapy to improve survival and quality of life for their patients. Today's decision improves insurance coverage for people with secondary MR who need treatment with MitraClip.

"Secondary mitral regurgitation generally impacts older individuals suffering from heart failure who rely on Medicare for their healthcare coverage," said Neil Moat, M.D., chief medical officer of Abbott's structural heart business. "CMS' decision to expand coverage for MitraClip marks a pivotal moment for people seeking a minimally invasive option that reduces mitral regurgitation and significantly improves their quality of life and chances of survival."

Following MitraClip's original approval by the FDA in late 2013, CMS provided coverage for Medicare patients with primary (degenerative) mitral regurgitation who needed treatment with MitraClip. Similarly, this revised NCD comes after the FDA's 2019 expanded indication for MitraClip to treat people with secondary MR. The decision also follows the highest MR reduction data for MitraClip reported to date: Recent 2020 data demonstrated MR reduction was consistently achieved with MitraClip in patients with either primary MR (to ≤1+ in 87.1%) or secondary MR (to ≤1+ in 90.1%) at 30 days.[1]

Supported by more than 17 years ofclinical trial data demonstrating safety and efficacy, and now on the fourth generation of product innovations, MitraClip is a first-of-its-kind device that clips together the leaflets, or flaps, of the mitral valve to reduce the backflow of blood and restore the heart's ability to pump oxygenated blood efficiently. The device provides symptom relief for both primary and secondary MR, with most patients being released from the hospital, on average, two days post-procedure.[2]

People with heart failure are at risk of developing significant secondary MR, a serious and progressive heart disease in which the two chambers of the left side of the heart become enlarged, thus preventing the mitral leaflets from closing normally and allowing blood to flow backwards through the heart. This can lead to reduced quality of life, recurrent hospitalizations and decreased survival.[3,4,5] Most heart failure patients with clinically significant secondary MR are treated with medication only, but data shows that these patients can benefit from reduction in MR with MitraClip.

"Approximately four million Americans suffer from MR, and it's estimated that two to three times as many patients may benefit from MitraClip for secondary mitral regurgitation than those for the primary form of the disease," said Michael Dale, senior vice president of Abbott's structural heart business. "We've worked tirelessly, for nearly two decades, to make MitraClip's leading technology available to patients suffering from mitral regurgitation, and CMS' expanded coverage allows our safe, effective and potentially life-saving treatment option to be available to the many more people who could benefit from our minimally invasive therapy."

This NCD revision is critically important to secondary MR patients, as most of those impacted by MR are older – with one in 10 adults age 75 or older experiencing MR[6] – and therefore relying on Medicare for their health insurance. Medicare coverage is limited to treatments, procedures and other healthcare items or services that CMS considers reasonable and necessary. National Coverage Determinations mandate coverage at the national level for all Medicare beneficiaries, including those participating in Medicare Advantage plans. Had CMS not revised the NCD to include the new secondary MR indication, Medicare patients with the secondary form of the disease would have continued to be ineligible for coverage and required to pay out of pocket for the procedure – creating a barrier to therapy access for patients.

About the MitraClip System
MitraClip is the world's first TEER (TMVr) therapy with more than 17 years of clinical experience and proven safety, survival and durable clinical outcomes. The device is approved in more than 75 countries worldwide, spanning regions in Asia, Africa, Europe, the Americas and Australia.

MitraClip is a small, clip-based device that repairs both primary and secondary MR without the need for open-heart surgery. The device is delivered to the heart through a vein in the leg and works by clipping together a portion of the leaflets of the mitral valve to reduce the backflow of blood, allowing the heart to pump blood more efficiently.

The MitraClip system has been commercially available in Europe since 2008 and was approved in the U.S. in 2013 for primary MR patients. In March 2019, the U.S. Food and Drug Administration (FDA) approved MitraClip for secondary MR patients based on results from the landmark COAPT™ (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation) Trial, which investigated MitraClip for treating secondary MR. COAPT showed a 47 percent relative reduction in hospitalizations and a 38 percent relative reduction in mortality for secondary MR patients. Both primary and secondary MR patients may benefit from MitraClip therapy based on this expanded indication for

MitraClip.

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

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

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 107,000 colleagues serve people in more than 160 countries.

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