Access To Abbott's MitraClip® System Expands In The U.S. With Medicare National Coverage Determination

- Medicare will Provide National Coverage for People with Severe Degenerative Mitral Regurgitation Deemed Too Sick for Surgery

- In Addition, Approval of New Technology Add-On Payment Recognizes the Substantial Clinical Benefits of MitraClip Therapy

ABBOTT PARK, Ill., Aug. 12, 2014 /PRNewswire/ -- The Centers for Medicare & Medicaid Services (CMS) recently issued a National Coverage Determination (NCD) that extends coverage for Medicare beneficiaries in the United States to Transcatheter Mitral Valve Repair with Abbott's (NYSE: ABT) MitraClip® System. The MitraClip System is a first-of-its-kind device that provides new hope for people with severe degenerative mitral regurgitation who are not good candidates for surgery. Treatment with MitraClip can significantly improve symptoms and quality of life by reducing the backward flow of blood through the mitral valve in the heart.

The NCD provides a national framework for Medicare coverage that can help people gain more timely access to the MitraClip treatment if they meet the eligibility requirements, which are based on CMS's analysis of the clinical evidence supporting the device. Multiple trials, published reports, and registries of people treated with the MitraClip device consistently demonstrate a positive safety profile, reduction in mitral regurgitation, improvement in symptoms, and reduction in hospitalizations for heart failure, even in some of the most ill and debilitated patients.

CMS also approved a New Technology Add-On Payment (NTAP) for the MitraClip System earlier this month, recognizing the substantial clinical benefits of this breakthrough innovation. The NTAP is designed to promote hospital adoption of new technologies that could benefit Medicare beneficiaries by enabling hospitals to obtain supplemental funding.

"We commend the extensive collaborative efforts of the CMS, FDA and medical societies in achieving this significant milestone of establishing a national coverage framework for Transcatheter Mitral Valve Repair," said Charles A. Simonton, M.D., FACC, FSCAI, divisional vice president, Medical Affairs, and chief medical officer, Abbott Vascular. "The National Coverage Determination and the New Technology Add-On Payment are important steps in helping people who need the MitraClip therapy gain timely access to treatment."

Mitral regurgitation is a debilitating, progressive and life-threatening disease in which a leaky mitral valve causes a backward flow of blood in the heart. The condition can raise the risk of irregular heartbeats, stroke, and heart failure, which can be deadly. Mitral regurgitation is common, affecting more than 4 million Americans – nearly one in 10 people aged 75 and above.[1] Open heart mitral valve surgery is the standard of care treatment, but many people are at prohibitive risk for an invasive procedure. Medications for the condition are limited to symptom management and do not stop the progression of the disease.

Abbott's MitraClip System repairs the mitral valve in people with severe degenerative mitral regurgitation without the need for an invasive surgical procedure. The device is delivered to the heart through the femoral vein, a blood vessel in the leg, and once implanted, allows the heart to pump blood more efficiently, thereby relieving symptoms and improving quality of life. People undergoing the MitraClip treatment typically experience short recovery times and short hospital stays of two to three days. MitraClip was approved by the U.S. Food and Drug Administration (FDA) in October 2013 and received CE Mark in 2008. After FDA approval, CMS initiated an NCD based on a multi-society request from the Society of Thoracic Surgeons (STS), American College of Cardiology (ACC), Society for Cardiovascular Angiography and Interventions (SCAI), and American Association for Thoracic Surgery (AATS).

About MitraClip

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR $\geq$ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation. More information, including important safety information, can be found at http://www.abbottvascular.com/docs/ifu/structural_heart/eIFU_MitraClip.pdf

About Abbott Vascular

Abbott Vascular is the world's leader in drug eluting stents. Abbott Vascular has an industry-leading pipeline and a comprehensive portfolio of market-leading products for cardiac and vascular care, including products for coronary artery disease, vessel closure, endovascular disease and structural heart disease.

About Abbott

Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 69,000 people.

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[1] Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a

population-based study. Lancet. 2006 Sep 16; 368(9540):1005-11.

SOURCE Abbott

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