FDA Advisory Committee Votes Favorably on Abbott's Minimally Invasive MitraClip® Device for Patients with Significant Mitral Regurgitation Who Are Too High Risk for Surgery

PR Newswire

ABBOTT PARK, Ill., March 20, 2013 /PRNewswire/ -- Abbott (NYSE: ABT [1]) today announced that the U.S. Food and Drug Administration (FDA) Circulatory System Devices Panel of the Medical Devices Advisory Committee has voted by majority (Yes: 5, No: 3) that the benefits of treatment with the MitraClip® device outweigh its risks in patients with significant symptomatic mitral regurgitation (MR) who have been determined by a cardiac surgeon to be too high risk for open mitral valve surgery and in whom existing co-morbidities would not preclude the expected benefit from correction of the MR.

Abbott's MitraClip device, which received CE Mark in 2008 and is commercially available in Europe and other international markets, is an investigational device in the United States. The device is delivered to the heart through the femoral vein, a blood vessel in the leg, and is designed to reduce MR by clipping together a portion of the leaflets of the mitral valve to allow the heart to more efficiently pump blood.

"We appreciate the FDA's dedication of time and resources to convene this advisory panel for MitraClip and for its review of this new and novel technology for high surgical risk patients suffering from the debilitating symptoms of significant mitral regurgitation," said Charles A. Simonton , M.D., FACC, FSCAI, divisional vice president, Medical Affairs, and chief medical officer, Abbott Vascular. "We are pleased with the outcome of today's panel, and we look forward to continuing discussions with the agency regarding the panel's comments."

On the separate question of whether there is reasonable assurance the device is safe, the panel voted Yes: 8, No: 0. On the question of whether there is reasonable assurance of efficacy, the panel voted Yes: 4, No: 5. The FDA will take into account the panel's advice in making its decision on whether to approve the MitraClip for the treatment of significant MR in the United States. The company expects a decision later this year.

The committee's recommendation followed a review of data from a large and growing body of clinical evidence (EVEREST II, EVEREST II High Risk and REALISM) in which the MitraClip therapy demonstrated positive and consistent results for high surgical risk patients suffering from the debilitating symptoms of significant MR, including a safe procedure, reduction in MR, reverse left ventricular remodeling, improvement in heart failure symptoms, improvements in quality of life, and reduced rates of re-hospitalization.

About Mitral Regurgitation
Mitral regurgitation (MR) is the most common type of heart valve insufficiency,[1] affecting approximately one in 10 people aged 75 years and older. The condition occurs when the leaflets of the mitral valve do not close completely, causing blood to flow backward and leak into the left atrium of the heart during the cardiac cycle. To maintain an adequate forward flow of blood throughout the body, the heart compensates by increasing the size of the left ventricle, the main pumping chamber of the heart. This requires the heart to work harder, and may ultimately lead to irregular heartbeats, stroke, heart attack or death. MR may also lead to heart failure, a potentially deadly condition that occurs when the heart is unable to pump sufficiently to distribute blood flow to meet the needs of the body.

About the MitraClip® Device
Abbott's MitraClip therapy is designed to reduce MR and provide clinical and quality-of-life benefits for patients suffering from the debilitating symptoms of significant MR by clipping together a portion of the leaflets of the mitral valve. The device is delivered to the heart through the femoral vein, a blood vessel in the leg. The heart beats normally during the procedure, and a heart-lung bypass machine is not required. By reducing MR, the therapy may allow the heart to recover from overwork and improve function, potentially halting the progression of heart failure and enabling patients to live a higher quality life.

The device received CE Mark in 2008 and is commercially available in 30 countries, with more than 8,000 patients treated to date. The European Society of Cardiology (ESC) 2012 heart failure guidelines and the ESC/European Association for Cardio-Thoracic Surgery 2012 guidelines for the management of valvular heart disease specify the MitraClip as a treatment option for high surgical risk patients with MR.

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 (NYSE: ABT [2]) 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 70,000 people.

Visit Abbott at www.abbott.com [3] and connect with us on Twitter at @AbbottNews.

[1] Nkomo VT, Gardin JM [4], Skelton TN [5], Gottdiener JS [6], Scott CG [7], Enriquez-Sarano M [8]. Burden of valvular heart diseases: a population-based study. Lancet. 2006 Sep 16; 368(9540):1005-11.

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