



Abbott Announces Launch of Catheter-Based MitraClip® System in Australia for Mitral Regurgitation, the Most Common Heart Valve Condition

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- First-of-its-Kind, Minimally Invasive Treatment Option for Select Patients

- Company Also Announces Study to Generate Additional Clinical and Health-Economic Data on the MitraClip System

ABBOTT PARK, Ill., March 30, 2011 /PRNewswire/ -- Abbott (NYSE: [ABT](#)) today announced the launch of the company's catheter-based MitraClip® system for the treatment of mitral regurgitation (MR) in Australia. The MitraClip device, which has received Therapeutic Goods Administration (TGA) approval, offers a new treatment option for patients suffering from MR, a debilitating heart valve condition.

Chronic, severe MR is often associated with heart failure and can result in death if left untreated. The MitraClip system represents an important therapeutic option for patients with this debilitating disease, many of whom may have no other treatment options.

The first patients were successfully treated in Australia by a multidisciplinary team including interventional cardiologist Eric Yamen, M.D.; cardiothoracic surgeon Jurgen Passage, M.D.; and echocardiologist Christopher Finn, M.D.; all at Sir Charles Gairdner Hospital in Perth.

"The availability of the MitraClip system provides physicians with a safe, minimally invasive treatment for mitral regurgitation that may provide new hope for many people for whom surgery is not an option," said Dr. Yamen.

"This therapy has the potential to improve the quality of life for many sick patients, enabling them to have a more active lifestyle."

The MitraClip system includes a catheter-based device that is delivered to the heart through the femoral vein, a blood vessel in the leg. The MitraClip therapy is designed to reduce significant MR by clipping together the leaflets of the mitral valve, one of the four valves of the heart. Significant MR is a debilitating condition in which the heart's ability to function continues to deteriorate over time, and may lead to irregular heartbeats, heart failure, stroke, heart attack or death. The condition traditionally has been managed with medications, which can relieve symptoms but do not address the underlying cause of the condition, or open-heart surgery. Many people who suffer from MR are not treated surgically(1) because they are not referred to surgery, are not sick enough, or are too frail for an invasive procedure.

"The MitraClip system is a breakthrough therapy that serves as a great example of Abbott's commitment to bringing innovative cardiac and vascular therapies to patients worldwide," said Robert Hance, senior vice president, vascular, Abbott. "Nearly 3,000 patients around the world have benefited from MitraClip treatment, and we are pleased that it is now commercially available in Australia."

New Clinical Study to Gather Additional Clinical and Health-Economic Data

Abbott today also announced the initiation of a new clinical study of the MitraClip device that will enroll up to 150 patients at up to 15 sites in Australia and New Zealand. The primary objective of the single-arm, prospective trial is to gather real-world clinical and health-economic outcome data to evaluate the long-term safety, efficacy and

economic value of the MitraClip system. Patients in the study will be evaluated at discharge and after 30 days and six, 12 and 24 months following the procedure.

Patients will be selected for inclusion in the study by a multidisciplinary team involving specialists in interventional cardiology, cardiac surgery and echocardiology.

David Muller, M.D., director of the Cardiac Catheterization Laboratories at St. Vincent's Hospital in Sydney, Australia, and Jurgen Passage, M.D., cardiothoracic surgeon at Sir Charles Gairdner Hospital in Perth, Australia, will serve as the principal investigators of the study.

About Mitral Regurgitation (MR)

MR is the most common type of heart valve insufficiency,(2) occurring when the leaflets of the mitral valve do not close completely, causing blood to flow backwards 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) to accommodate the increase in the volume of blood it is pumping. The chronic volume overload caused by MR requires the heart to work harder and may ultimately lead to heart failure and other complications. MR traditionally has been managed with drugs or open-heart surgery, depending on an individual patient's severity of MR and risk factors.

About the MitraClip Technology and Procedure

Abbott's proprietary MitraClip system is designed to reduce significant MR by clipping together the leaflets of the mitral valve, one of the four valves of the heart. The catheter-based MitraClip device is delivered to the heart through the femoral vein, a blood vessel in the leg. The heart beats normally during the procedure, and therefore does not require a heart-lung bypass machine. After treatment, patients are usually home within two to three days and have been observed to recover quickly. The safety and efficacy of the MitraClip system was evaluated in EVEREST II, the first randomized clinical trial to compare a catheter-based mitral valve device to mitral valve surgery.

The MitraClip system received CE Mark in March 2008 and is commercially available in Europe, Turkey, Israel and Australia. The first-in-man clinical trial of the MitraClip system was conducted in the United States, where it is an investigational device currently under review for approval by the U.S. Food and Drug Administration.

About Abbott Vascular

Abbott Vascular is a global leader in cardiac and vascular care with market-leading products and an industry-leading pipeline. Abbott Vascular offers a comprehensive cardiac and vascular devices portfolio, including products for coronary artery disease, vessel closure, endovascular disease, and structural heart disease.

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs nearly 90,000 people and markets its products in more than 130 countries.

(1) Bach DS, Awais M, Gurm HS, et al. Failure of guideline adherence for intervention in patients with severe mitral regurgitation. *J Am Coll Cardiol* 2009; 54:860-865.

(2) 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):1007.

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