ABBOTT BEGINS U.S. PIVOTAL TRIAL FOR THE TENDYNE MITRAL VALVE REPLACEMENT SYSTEM TO TREAT PATIENTS WITH HEART VALVE DISEASE

- Investigational Tendyne device is first and only repositionable and fully retrievable mitral valve replacement

- Valve is designed to allow doctors to replace damaged mitral heart valves without open-heart surgery

- Early results from separate global study are promising

ABBOTT PARK, Ill., July 26, 2018 /PRNewswire/ -- Abbott (NYSE: ABT) today announced it has initiated a pivotal clinical study in the U.S. of its Tendyne Transcatheter Mitral Valve Replacement (TMVR) system for the treatment of mitral regurgitation. The trial will evaluate the safety and efficacy of the treatment in patients suffering from mitral regurgitation (MR), known as a leaky heart valve. The investigational Tendyne device is the first and only mitral valve replacement that can be repositioned and fully retrieved, allowing the surgeon to precisely place the device during implantation, which could improve patient outcomes. Since the approval of the MitraClip® device in 2008, Abbott has led the development of minimally invasive solutions for difficult-to-treat mitral regurgitation, and the Tendyne device is designed to offer a new treatment option for MR patients requiring a minimally invasive replacement valve.

The study, called SUMMIT, will enroll up to 1,010 patients at 80 sites in the U.S., EU and Canada to evaluate if treatment with the Tendyne TMVR system is safe and effective for patients suffering from severe MR. Jason Rogers, M.D., professor and director of interventional cardiology at U.C. Davis Medical Center in Sacramento, Calif., and Gorav Ailawadi, M.D., professor of surgery and chief of cardiac surgery at the University of Virginia, are co-principal investigators of the study, which will evaluate a composite endpoint of death, cardiovascular hospitalization, stroke or reoperation at one year. The first several patients in the trial were treated at Ascension's Via Christi Hospital St. Francis in Wichita, Kan. and the West Virginia University Heart and Vascular Institute in Morgantown, W.Va.

Mitral regurgitation is a debilitating, progressive and life-threatening disease in which the heart's mitral valve does not close completely, causing blood to flow backward and leak into the left atrium of the heart. The condition can raise the risk of irregular heartbeats and stroke, and if left untreated, could ultimately lead to heart failure and death. Nearly one in 10 people over the age of 75 have moderate to severe MR[1], which is often difficult to diagnose. Abbott's MitraClip is the leading approved device to repair a leaking mitral valve, but there are currently no approved minimally invasive therapies to replace the mitral valve.

The Tendyne valve may provide a life-saving treatment option for MR patients by replacing their native mitral valve without open-heart surgery to reduce their heart failure symptoms. The device is a tri-leaflet, bioprosthetic valve available in multiple sizes, and is stabilized by a pad and a tether mechanism that holds the pad in place where it's been implanted inside the native valve. As the first and only repositionable and fully retrievable replacement valve, Tendyne can conform to a broad range of anatomies, which may allow for better outcomes and procedural ease-of-use.

"The mitral valve is known for its complex anatomy and, as a result, managing mitral regurgitation can be challenging, especially in elderly or frail patients for whom there are limited to no treatment options," said Bassem M. Chehab, M.D., medical director of Via Christi's structural heart program, who implanted the first patient in the study with the Tendyne valve. "I'm encouraged by promising early results from the global study and excited about the potential for the Tendyne device to advance the field of transcatheter mitral valve replacement in the U.S. by providing another option for MR patients needing a minimally invasive alternative."

Abbott recently shared data at EuroPCR, the annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), that showed positive results from the first 100 patients treated in a global study of the Tendyne device. Results showed that, at 30 days, patients treated with Tendyne had a significant reduction in symptoms of MR and low mortality rates.

"Transcatheter mitral valve replacement represents a new frontier in treating people whose valve does not close properly and who would benefit from a replacement valve instead of repair," said Michael Dale, vice president of Abbott's structural heart business. "Abbott established the market for minimally invasive mitral valve repair with MitraClip, showing the safety and viability of a non-surgical repair and paving the way for other catheter-based devices to treat structural heart diseases. Our scientists and engineers are building on our expertise to advance transcatheter mitral valve replacement with our Tendyne technology to provide a needed treatment option."

In addition to the U.S. pivotal trial, Abbott will initiate a separate feasibility study of the Tendyne system in patients with severe mitral annular calcification (MAC), a condition in which calcium accumulates along and beneath the mitral valve annulus, a ring-like structure that separates the top and bottom chambers of the left side of the heart.

Abbott is a global leader in the treatment of mitral regurgitation with the MitraClip device, which has been on the market in the EU since 2008 and in the U.S. since 2013 to repair the mitral valve. More than 65,000 patients have been treated with this first-of-its-kind minimally invasive therapy, that is delivered to the heart through a blood vessel in the leg. Abbott has continued to innovate the treatment of mitral regurgitation to ensure patients have minimally invasive options to open-heart surgery.

For U.S. Important Safety Information on MitraClip, visit http://mitraclippossibilities.com/#isi-sec.

The Tendyne Transcatheter Mitral Valve Replacement system is an investigational device only.

About Abbott:
At Abbott, we're committed to helping people live their best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 99,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

Connect with us at www.abbott.com, on Facebook at www.facebook.com/Abbott and on Twitter @AbbottNews and @AbbottGlobal.

[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. https://www.ncbi.nlm.nih.gov/pubmed/16980116

SOURCE Abbott

For further information: Abbott Media: Mary Kokkinen, (408) 444-2401; Abbott Financial: Mike Comilla, (224) 668-1872