ABBOTT LEADS WAY IN FIRST CLINICAL TRIAL OF MINIMALLY INVASIVE CLIP-BASED REPAIR SYSTEM FOR LEAKY TRICUSPID HEART VALVES

-Trial will study efficacy and safety of a new transcatheter clip-based repair system for tricuspid valve disease, an undertreated, life-altering condition

-First trial of its kind to evaluate minimally invasive treatment using clip technology for moderate or severe tricuspid regurgitation

ABBOTT PARK, Ill., Aug. 9, 2017 -- Abbott today announced that the first patient has been enrolled in a clinical study to evaluate a minimally invasive clip-based repair system for treating people with moderate or severe tricuspid regurgitation (TR), a common condition affecting the right side of the heart. The first patient was enrolled at Abbott Northwestern Hospital by Dr. Paul Sorajja, M.D., cardiologist at Minneapolis Heart Institute and Abbott Northwestern Hospital.

The transcatheter tricuspid valve repair (TTVR) system builds upon more than a decade of development for Abbott's proven MitraClip System, which has shown to predictably and effectively treat mitral regurgitation, a similar disease impacting the left side of the heart.

Tricuspid regurgitation is a condition in which the valve between the heart's two chambers on the right side does not close properly, resulting in a backward flow of blood into the right atrium. The consequences of leaving it untreated can be substantial – people often develop other conditions such as atrial fibrillation, heart failure and, ultimately, death. Currently, there are no approved minimally invasive treatments for people with moderate or severe tricuspid regurgitation.

"Current pharmacological and surgical treatment options are not meeting the needs of people living with tricuspid regurgitation," said Georg Nickenig, M.D., Ph.D., professor and chief, Department of Cardiology, University Hospital, Bonn, Germany, and lead investigator of the study. "Abbott's MitraClip has shown positive results for mitral regurgitation, and we hope this study shows that a similar clip-based technology may effectively treat people with tricuspid regurgitation."

The trial is expected to support Abbott's application for CE Mark in Europe for a clip-based transcatheter tricuspid valve repair system.

"As a leader in structural heart therapies, Abbott is exploring new ways to treat people with heart valve diseases," said Charles Simonton, M.D., chief medical officer and divisional vice president, Global Medical Affairs, for Abbott's vascular and structural heart businesses. "The investigational medical device that will be used in this study builds on years of learnings and knowledge using our clip-based device for treating mitral regurgitation. We look forward to the results of the trial to determine if this new minimally invasive technology has the potential to benefit people living with tricuspid regurgitation just as predictably."

The study, called TRILUMINATE, is a prospective, single-arm, multi-center study designed to evaluate the performance of clip-based technology in approximately 75 symptomatic patients at 25 sites across the U.S. and Europe. The primary endpoints are an echocardiographic tricuspid regurgitation reduction of ≥ 1 grade at 30 days post-procedure, and the assessment of major adverse events at six months.

For important safety information on MitraClip, please visit: https://mitraclip.com/#isi.

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