ABBOTT'S TRICLIP™ BECOMES FIRST DEVICE OF ITS KIND TO RECEIVE CE MARK FOR MINIMALLY INVASIVE TRICUSPID VALVE REPAIR

- CE Mark for TriClip represents an important treatment option for people with severe tricuspid regurgitation, a difficult-to-manage heart condition

- New system offers a proven safe and effective minimally invasive non-surgical solution

- The TriClip System leverages Abbott's proven clip-based technology used in its MitraClip™ transcatheter mitral valve therapy

ABBOTT PARK, Ill., April 9, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that its TriClip™ Transcatheter Tricuspid Valve Repair System has received CE Mark and is now approved for use in Europe and other countries that recognize CE Mark as a non-surgical treatment for people with a leaky tricuspid valve, a condition known as tricuspid regurgitation (TR). With the CE Mark designation, Abbott's TriClip device is the first minimally invasive, clip-based tricuspid valve repair device to be commercially available in the world. Abbott is a global leader in developing transcatheter treatments for heart valve disorders and has brought to market three first-in-class therapies for structural heart disease: MitraClip for mitral valve repair, Tendyne™ for mitral valve replacement, and now TriClip to treat the tricuspid valve.

The tricuspid valve, often referred to as the "forgotten heart valve," has three leaflets that control the flow of blood between the two chambers on the right side of the heart. When those leaflets do not close properly, blood can flow in the reverse direction – known as regurgitation – forcing the heart to work harder. When left untreated, TR can lead to conditions such as atrial fibrillation, heart failure, and ultimately, death. The condition is difficult to treat, however, and options for patients have historically been extremely limited. People with TR are typically older and suffer from multiple co-morbidities, making open-heart surgery a high-risk procedure.[i]

The TriClip procedure repairs the tricuspid valve without the need for open-heart surgery. The device is delivered to the heart through the femoral vein in the leg and works by clipping together a portion of the leaflets of the tricuspid valve to reduce the backflow of blood. This approach allows the heart to pump blood more efficiently, relieving symptoms of TR and improving a person's quality of life.

"Patients suffering from severe tricuspid regurgitation are extremely ill and have very few treatment options," said Georg Nickenig, M.D., Ph.D., professor and chief, Department of Cardiology, University Hospital, Bonn, Germany, and lead investigator of the TRILUMINATE trial, which generated strong data that helped lead to the CE Mark of TriClip. "Abbott's TriClip could profoundly impact how physicians treat these patients. The therapy is backed by data proving safety and performance, durability, and improved patient quality of life."

The CE Mark for TriClip follows positive six-month data from Abbott's pivotal TRILUMINATE study examining edge-to-edge repair technique using TriClip, which was published in *The Lancet* in November 2019. The study demonstrated that TriClip reduced severity of TR and was associated with strong improvement in functional capacity and in quality of life at six months.

"Tricuspid regurgitation is a highly prevalent, yet seldom treated disease, which is why this approval is a significant milestone for the healthcare community. TriClip has the potential to fill a treatment gap and transform how doctors are able to help people with tricuspid regurgitation," said Michael Dale, senior vice president of Abbott's structural heart business. "Our clip-based technology provides clinicians a life-changing, proven safe, simple, and effective option to treat people suffering from a crippling and life-threatening disease."

TriClip builds upon the proven success of Abbott's MitraClip device, which treats people with leaky mitral valves, or mitral regurgitation (MR). TriClip leverages the same clip-based technology as MitraClip but has a differentiated delivery system designed specifically for delivery to the tricuspid valve. A new, steerable guiding catheter system adapts to the right side of the heart, where the tricuspid valve resides, enabling the physician to effectively grasp and clip the leaflets of the tricuspid valve. Additionally, the TriClip device is available in two different sizes (NT and XT) to accommodate different patient anatomies.

The MitraClip system is the first and only transcatheter mitral valve therapy with more than 16 years of clinical experience and proven safety, survival and durable clinical outcomes. More than 100,000 patients have been treated worldwide with the device. Abbott also recently announced CE Mark approval of its Tendyne Transcatheter Mitral Valve Implantation System, a minimally invasive valve replacement option to add to its portfolio of mitral solutions.

For U.S. important safety information on MitraClip, visit: https://www.structuralheartsolutions.com/us/mitraclip-isi.

The TriClip Transcatheter Tricuspid Valve Repair System is an investigational device only in the U.S.

The Tendyne Transcatheter Mitral Valve Implantation System is an investigational device only in the U.S.

About Abbott:
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[i] Topilsky, et al *JACC Cardiovascular Imaging* 2018.

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