# Abbott Receives U.S. Approval Of Next-Generation MitraClip™, Bringing New Enhancements To Abbott's Leading MitraClip Platform

- U.S. approval for MitraClip G4 offers a next-generation approach to mitral valve repair

- G4 includes new clip sizes and an enhanced leaflet grasping feature

ABBOTT PARK, Ill., July 15, 2019 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the company has received U.S. Food and Drug Administration (FDA) approval for the most advanced MitraClip™ heart valve repair device to treat mitral regurgitation. The latest approval for the fourth-generation MitraClip device, MitraClip G4, puts new enhancements into the hands of physicians across the U.S. by delivering an expanded range of clip sizes, an alternative leaflet grasping feature and facilitation of procedure assessment in real time to offer doctors further options when treating mitral valve disease.

The MitraClip device repairs leaky mitral valves without open-heart surgery and is delivered to the heart through a small incision in the leg. The device clips portions of the leaflets, or flaps, of the mitral valve together to reduce the backflow of blood (known as mitral regurgitation, or MR), restoring the heart's ability to pump oxygenated blood more efficiently. To date, MitraClip has helped treat more than 80,000 people worldwide suffering from both primary and secondary MR and is supported by the industry's most extensive body of clinical evidence, including the recent results of the landmark COAPT™ Trial published in *The New England Journal of Medicine* in September 2018.

As part of an ongoing, patient-centric product development cadence, Abbott has expanded MitraClip to a total of four clip sizes – now including clips with wider grasping area – to provide physicians additional options for treatment. MitraClip G4 also offers independently controlled grippers that allow physicians to grasp one or both leaflets during the procedure, known as Controlled Gripper Actuation™.

"We are continually innovating the MitraClip technology based on the experience of the physicians implanting the device so we can truly help them improve the lives of their patients," said Neil Moat, M.D., chief medical officer of Abbott's structural heart business. "With the fourth generation of MitraClip, we set out to build a system that would help physicians individualize the therapy to each patient and deliver even more features that can treat both primary and secondary mitral regurgitation."

In addition to four clip sizes and the leaflet grasping feature, the latest generation of MitraClip offers the benefit of an upgraded catheter to allow integrated real-time continuous left atrial pressure monitoring during implant. The feature allows physicians to use a commercially available pressure monitor integrated into the MitraClip catheter to continuously monitor and confirm MR reduction during the implant procedure and help them determine whether MitraClip should be repositioned or placed differently to optimize patient outcomes.

**About the MitraClip System**
The MitraClip system has been commercially available in the U.S. since 2013 and in Europe since 2008. With more than 15 years of clinical experience and over 80,000 patients treated worldwide, the MitraClip system is the first and only transcatheter mitral valve therapy with proven safety and survival, and durable clinical outcomes.

MitraClip was approved in the U.S. in 2013 for primary MR patients. In March of this year, FDA approved MitraClip for secondary MR patients based on results from the COAPT Trial, which investigated MitraClip for treating secondary MR. A landmark trial, COAPT showed a 47% relative reduction in hospitalizations and a 38% relative reduction in mortality. Both primary and secondary MR patients may benefit from MitraClip therapy based on this expanded indication for MitraClip. Since the initial approval, Abbott has introduced two newer generations, G2, G3 and now G4, to support patient care.

Abbott is the global leader in developing transcatheter mitral valve technologies as alternatives to open-heart surgery. Building upon its success with the MitraClip device and many years of mitral valve experience and clinical evidence, Abbott is also leading the way in novel, transcatheter devices by investing in the development and clinical study of new mitral valve replacement technologies.

*For more information on MitraClip, visit:www.structuralheartsolutions.com.*

*For U.S. Important Safety Information about MitraClip, visit:https://www.structuralheartsolutions.com/us/mitraclip-isi.*

**About Abbott**
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 103,000 colleagues serve people in more than 160 countries.

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