FDA Approves Abbott's Epic™ Plus Tissue Valves For People In Need Of Mitral Or Aortic Valve Replacement

- New enhancements to Abbott's Epic valve – the most widely used mitral tissue heart valve in the U.S. and globally – can improve implantation and allow compatibility for future transcatheter valve procedures

- Epic Plus designed to help patients with more complex cases of aortic or mitral regurgitation or stenosis

- Latest device builds on history of surgical valve replacement as a reliable and critical therapy option for patients with valvular heart disease

ABBOTT PARK, Ill., Sept. 22, 2021 — Abbott today announced that the U.S. Food and Drug Administration (FDA) has approved the company's Epic™ Plus and Epic Plus Supra Stented Tissue Valves to improve therapy options for people with aortic or mitral valve disease. These next-generation devices build off Abbott's Epic surgical valve platform – which has a decades-long history of safety and strong clinical outcomes – and include innovations that make implantation of the valve and future cardiac interventions easier.

Heart valve disease occurs when one or more of the heart's four valves doesn't open or close properly, disrupting blood flow to the body, and most commonly impacts the aortic and mitral valves. When diseased or damaged heart valves can't be repaired, they may be surgically replaced with either mechanical or bioprosthetic (tissue) valves in an open-heart surgical procedure. Bioprosthetic valves like Epic Plus do not require long-term use of blood-thinner medication, making them the recommended option for people who can't take blood thinners or are over 70 years of age (a group that has an increased bleeding risk from taking these medicines).

More than 100,000 people in the U.S. have conventional heart valve surgeries each year[i] which are often life-saving procedures. The approval of the new Epic Plus tissue valves provides an important treatment option for patients undergoing valve replacement surgery without the need for long-term blood thinners, while providing a durable solution that allows for reinterventions as needed.

"Doctors and patients have long depended on the Epic valve platform to help improve the quality of life for people in need of a surgical heart valve replacement," said Vinayak Bapat, M.D., chief of Cardiothoracic Surgery at Abbott Northwestern Hospital. "With advancements made to Epic Plus, physicians can be assured of a reliable, longer-term solution for their patients needing a replacement heart valve that will also allow for future cardiac interventions if necessary due to the valve's accommodating design."

Enhancements to Epic Plus include more radiopaque markers (reference points that are visible on radiographic scans) that make it easier for doctors to navigate if future transcatheter procedures are needed. In keeping with the Epic surgical valve platform, the new valves are designed to deliver long-term performance and durability due to Abbott's unique anticalcification technology. The Epic Plus Mitral holder, which helps to ensure precise insertion of the valve, also has a lower profile so physicians have a better view of the device for accurate placement during implantation. The device can be implanted in the aortic or mitral valve position and in patients with more complicated anatomies.

"Whether it's developing new treatment options or improving upon our existing proven therapies, Abbott is constantly striving to deliver innovative solutions to address life-threatening heart conditions," said Michael Dale, senior vice president of Abbott's structural heart business. "This FDA approval affirms our commitment to advancement of the Epic Platform and our mission to help people live better lives through better health."

The Epic Plus Stented Tissue Valves are the latest addition to Abbott's portfolio of surgical tissue and mechanical heart valves. The company is also the global leader in mechanical heart valves with more than three million people treated worldwide.

For U.S. important safety information on Epic Plus, visit http://abbo.tt/EpicPlusISI.

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 109,000 colleagues serve people in more than 160 countries.

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[i] Texas Heart Institute. Valve Repair or Replacement. June 2021.

For further information: Abbott Media: Cynthia Kong (669) 400-6879; Abbott Financial: Mike Comilla (224) 668-1872