Abbott Receives FDA Approval For Minimally Invasive Portico™ With FlexNav™ TAVR System To Treat Patients With Aortic Valve Disease

- Transcatheter aortic valve replacement (TAVR) procedure treats people with symptomatic, severe aortic stenosis who are at high or extreme risk for open-heart surgery

- With Portico approval, Abbott offers the industry's most comprehensive portfolio of structural heart solutions in the U.S.

ABBOTT PARK, Ill., Sept. 20, 2021 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved the company's Portico™ with FlexNav™ transcatheter aortic valve replacement (TAVR) system to treat people with symptomatic, severe aortic stenosis who are at high or extreme risk for open-heart surgery. With this latest TAVR (also referred to as TAVI, or transcatheter aortic valve implantation) advancement, Abbott continues to offer the industry's leading portfolio of structural heart solutions that include innovative, minimally invasive therapies to repair or replace diseased or damaged heart valves or close openings in the heart.

Aortic stenosis is one of the most common and life-threatening heart valve diseases. It occurs when the aortic valve's opening narrows and restricts blood flow from the left ventricle to the aorta.[1] Patients with the disease can experience breathlessness, chest pressure or tightness, fainting, palpitations, fatigue, and heart murmurs. The condition can ultimately lead to heart failure.[2] While many people don't have noticeable symptoms, more than one in eight aged 75 and older has moderate or severe aortic stenosis, which reduces the heart's pumping ability.[3] Prior to TAVR, the standard of care for severe aortic stenosis was surgical aortic valve replacement, but not all patients were candidates for open-heart surgery.

"For people in the U.S. suffering from aortic stenosis and unable to have surgery, the Portico with FlexNav system offers a safe and effective treatment option," said Raj Makkar, M.D., associate director of Interventional Technologies at Cedars-Sinai's Smidt Heart Institute, who served as co-principal investigator for the study that led to FDA approval. Gregory Fontana, M.D., national director, Cardiovascular Research at Hospital Corporation of America Research Institute and national director, Cardiothoracic Surgery at Hospital Corporation of America, also served as co-principal investigator of the Portico IDE study.

With years of experience globally, Portico is a self-expanding TAVR valve with intra-annular (within the native valve) leaflets that help provide optimal blood flow (hemodynamics) when placed inside a patient's natural valve. The structure of the replacement valve also preserves access to the critical coronary arteries for future coronary interventions. The Portico device is implanted using Abbott's FlexNav delivery system, which features a slim design to accommodate different patient anatomies and small vessels, and optimizes flexibility, ease of tracking and precision of valve placement.

"With the approval of our TAVR therapy in the U.S., physicians now have access to an even more robust set of solutions to treat structural heart disease," said Michael Dale, senior vice president of Abbott's structural heart business. "This latest and important introduction of Portico with FlexNav represents another milestone in our work to advance our mission to restore health and improve quality of life so more people can get back to living fuller lives."

For more information on Portico, please visit https://abbo.tt/Portico.

For U.S. important safety information on Portico, visit https://abbo.tt/PorticoISI.

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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[1] American Heart Association. Aortic Stenosis Overview. 2020.

[2] Osnabrugge RLJ, Mylotte D, Head SJ, et al; Aortic Stenosis in the Elderly: Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement: A Meta-Analysis and Modeling Study. Journal of the American College of Cardiology. 2013; 11:1002-1012.

[3] Nkomo VT, Gardin JM, Skelton TN, et al. Burden of valvular heart diseases: a population-based study. Lancet 2006;368:1005-11

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