Abbott's Navitor™ TAVI System Receives CE Mark For Expanded Indication To Treat More People With Aortic Stenosis

- Navitor is now approved as a minimally invasive alternative to surgery for patients in Europe with symptomatic, severe aortic stenosis (a common and life-threatening heart valve disease) who are at low or intermediate surgical risk
- CE Mark is based on safety and effectiveness data from the VANTAGE trial presented at the European Society of Cardiology (ESC) Congress 2025 and simultaneously published in *JACC: Cardiovascular Interventions*
- Updated guidelines announced for the management of valvular heart disease provide further support for mitral and tricuspid therapies like MitraClip™ and TriClip™ for leaky heart valves

ABBOTT PARK, Ill., Aug. 29, 2025 /PRNewswire/ -- Abbott (NYSE: ABT) today announced it has received CE Mark in Europe for an expanded indication for the company's Navitor™ transcatheter aortic valve implantation (TAVI) system to treat people with symptomatic, severe aortic stenosis who are at low or intermediate risk for open-heart surgery. Abbott previously received CE Mark in 2021 for Navitor to treat people with symptomatic, severe aortic stenosis who are at high or extreme surgical risk. With this new approval, Navitor is available in Europe for patients across all surgical risk categories, significantly expanding the number of people that can be treated with the device.

The expanded indication was supported by favorable safety and effectiveness outcomes from the VANTAGE study, which was presented as a late breaker at the European Society of Cardiology (ESC) Congress 2025, held in Madrid (Aug. 29-Sept. 1, 2025). These data were simultaneously published in *JACC: Cardiovascular Interventions*.

"The VANTAGE study provides the scientific backbone for expanding Navitor's indication to low- and intermediate-risk patients. The data are exceptional across both populations, confirming that the Navitor valve performs precisely as designed," said Nicolas van Mieghem, M.D., medical director of the department of interventional cardiology at the Thoraxcenter, Erasmus University Medical Centre, in the Netherlands, who serves as principal investigator of the VANTAGE trial. "Up to 50% of younger patients with aortic stenosis will also get coronary artery disease in later years, and Navitor's design preserves options and ability for lifetime disease management if future cardiac interventions are required."

Aortic stenosis occurs when the aortic valve's opening narrows, restricting blood flow to the body. Left untreated, it can lead to heart failure and death. The Navitor TAVI device replaces the aortic valve through a minimally invasive procedure and is delivered to the heart through a small incision in the leg. The performance of such devices is measured by blood flow through the valve, referred to as hemodynamics.

Key findings from the VANTAGE trial
The late-breaking data presented at ESC from Abbott's VANTAGE study showed Navitor met all safety and effectiveness primary endpoints, supporting its expansion to treat people with symptomatic, severe aortic stenosis who are at low or intermediate surgical risk. Key findings include:

- **Excellent safety.** In the first 262 patients with 12-month follow-up completed, there was a low rate (2.3%) of all-cause mortality or fatal stroke/stroke with disability.
- **Proven effectiveness.** No patients at 30 days had moderate or greater PVL (paravalvular leak or backflow of blood around the valve) and only 13.6% had mild PVL, a rate that is considered low.[1,2,3,4]
- **High technical success:** There was a high rate of technical success (97%) with no procedural deaths.
- **Sustained hemodynamic performance.** Excellent hemodynamic performance was seen at 12 months.

"Navitor is a strong example of how Abbott continues to evolve its structural heart portfolio to meet the growing demand for minimally invasive alternatives to open-heart surgery," said Sandra Lesenfants, senior vice president of Abbott's structural heart business. "Aortic stenosis is a life-threatening condition that can progress rapidly, and this expanded indication for Navitor means that patients have more options that can help reduce their symptoms and improve their lives."

The Navitor TAVI system is currently approved in the U.S. to treat people with symptomatic, severe aortic stenosis who are at high or extreme risk for open-heart surgery.

Updated transcatheter edge-to-edge repair (TEER) guidelines
During ESC Congress 2025, ESC and the European Association for Cardio-Thoracic Surgery (EACTS) announced new guidelines for the management of valvular heart disease. Mitral valve TEER was upgraded from a treatment that should be considered (IIa) to a recommended treatment (Class Ia) for selected patients with severe functional (or secondary) mitral regurgitation (MR). Tricuspid valve TEER was also upgraded from a treatment that may be considered (IIb) to a treatment that should be considered (Class IIa) for selected patients with severe functional tricuspid regurgitation (TR).

With these updated guidelines, there's additional support for the use of MitraClip™ and TriClip™ for MR and TR patients that is backed by evidence from multiple clinical studies, including COAPT, TRILUMINATE, TRILUMINATE Pivotal, bRIGHT, RESHAPE-HF2 and TRI.fr, that demonstrate the therapies' effectiveness.

For U.S. important safety information about MitraClip and TriClip, visit https://abbo.tt/TEERG5ISI.

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 114,000 colleagues serve people in more than 160 countries.

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