Abbott Initiates VOYAGER Clinical Trial For Investigational Encantor™ Software-Guided Balloon-Expandable TAVI System To Treat Aortic Stenosis

- Abbott's Encantor system includes software-guided deployment technology designed to help optimize valve expansion to the patient's unique anatomy, supporting precise implantation and consistent valve performance
- Encantor early feasibility study data will be presented at PCR London Valves 2026

ABBOTT PARK, Ill., Nov. 19, 2026 /PRNewswire/ -- Abbott (NYSE: ABT), the global healthcare leader, announced today it has initiated the VOYAGER CE clinical trial evaluating the safety and efficacy of its investigational Encantor™ transcatheter aortic valve implantation (TAVI) software-guided balloon-expandable system for treating symptomatic severe aortic stenosis. The first enrollment in the VOYAGER CE study occurred at Macquarie University in Sydney, Australia, led by Stephen Worthley, M.B.B.S, Ph.D.

The prospective, single-arm, pre-market study will enroll up to 300 patients in Europe and Australia with symptomatic severe aortic stenosis caused by severe calcium buildup in the aortic valve. The study will be the basis to seek approval for use in Europe and Australia.

"TAVI has transformed the treatment of severe aortic stenosis, but physicians continue to seek technologies that make procedures more predictable and allow treatment to be tailored to individual patients," said Didier Tchétché, M.D., director of the structural heart disease department, Clinique Pasteur, Toulouse, France, and co-principal investigator of VOYAGER CE. "Encantor's balloon-expandable design and software-guided approach are intended to give physicians greater control and procedural confidence."

Encantor designed to treat narrowing of aortic valve

Aortic stenosis occurs when calcium builds up in the aortic valve – which controls the flow of oxygen-rich blood to the body – and causes it to narrow. Eventually, the heart must work harder to pump blood through the narrowed valve. Left untreated, it can lead to heart failure and death.

The investigational Encantor system works by crimping the new heart valve on a deflated surgical balloon. The balloon with the mounted valve is then inserted into the body and guided through a catheter in an artery in the groin to the heart. Once properly positioned inside the diseased aortic valve, software-guided deployment helps customize expansion of the valve to the patient's unique anatomy for a more precise fit. Once the new valve is in place, it takes over the function of the patient's damaged native valve. The balloon is then deflated and removed from the body.

Continued research and expansion of TAVI solutions is key as the needs of physicians and patients evolve. Leveraging insights from physicians, the latest technology advancements and key learnings from the company's Navitor™ TAVI product portfolio, Abbott developed the differentiated Encantor TAVI platform to enhance procedural ease of use and controlled, precise deployment, while offering optimal blood flow (hemodynamics) through the valve.

Early feasibility study characterizes Encantor safety and functional outcomes

Six-month data on safety, hemodynamic and functional outcomes from the Encantor early feasibility study and an overview of the Encantor TAVI system will be presented during an innovation session on Nov. 22 at PCR London Valves 2026 (Nov. 22-24, 2026).

Findings from the early feasibility study supported initiation of the VOYAGER CE study.

"Our ambition is to give physicians the right technology for each patient," said Sandra Lesenfants, senior vice president of Abbott's structural heart business. "Our investigational Encantor system complements our Navitor self-expanding platform with a balloon-expandable option designed around physician insights, precise deployment and procedural ease of use. Advancing VOYAGER CE brings us another step closer to offering physicians a broader portfolio of structural heart solutions."

Upon successful completion of clinical trials and receipt of applicable regulatory approvals, the Encantor system will further expand Abbott's comprehensive structural heart portfolio, offering physicians an additional management option to address the needs of patients.

The Encantor balloon-expandable TAVI is investigational only and not for use anywhere in the world, including the U.S., Australia, Canada or Europe. Abbott plans to initiate a pivotal trial in the U.S. in the coming months.

Frequently Asked Questions:

What is aortic stenosis?
Aortic stenosis is a heart condition in which the aortic valve becomes narrowed and stiff, blocking normal blood flow from the left ventricle into the aorta and the rest of the body. If left untreated, it can cause symptoms, such as chest pain, shortness of breath and fainting, and even weaken the heart and become life-threatening.

How does the investigational Encantor system work?
The investigational Encantor system is a software-guided balloon-expandable transcatheter aortic valve implantation (TAVI) device that works by crimping the new heart valve on a deflated balloon. The balloon with the mounted valve is then inserted into the body through an artery in the groin and routed up to the heart. Once properly positioned inside the narrowed heart valve,

software-guided deployment helps customize expansion of the valve to the patient's unique anatomy for a more precise fit. Once the new valve is in place, it takes over the function of the patient's narrow native heart valve. The balloon is then deflated and removed from the body.

What is the VOYAGER CE clinical trial?
The VOYAGER CE trial is a prospective, single-arm, pre-market clinical study that will enroll people who have symptomatic heart disease due to aortic stenosis caused by severe calcium buildup in the valve. The study, which will enroll up to 300 patients in Europe and Australia, will be the basis for CE Mark approval in the Europe. The Encantor balloon-expandable transcatheter aortic valve implantation (TAVI) is investigational only and not for use anywhere in the world, including the U.S., Australia, Canada or Europe.

What is the difference between Encantor and Abbott's current TAVI solution, Navitor?
The key difference is how the valves expand: the investigational Encantor system uses a balloon and software guidance to expand the replacement valve inside the narrowed native valve. Abbott's current Navitor TAVI system uses a self-expanding valve. Both approaches deliver a replacement valve through a catheter rather than open-heart surgery. If approved, Encantor would complement Navitor, giving physicians more options to address individual patient anatomy and clinical needs.

For U.S. important safety information on Navitor, visit https://abbo.tt/NavitorISI.

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 122,000 colleagues serve people in more than 160 countries.

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For further information: Abbott Media: Brent Tippen, (415) 672-8525, Abbott Financial: Mike Comilla, (224) 668-1872

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