Abbott Initiates Pivotal Trial For Cephea™ Device, An Innovative Treatment For Mitral Heart Valve Disease

- CROWN-MV trial will evaluate the safety and effectiveness of investigational Cephea mitral valve replacement device
- Abbott's Cephea is designed to provide a new, minimally invasive option for treating mitral valve disease, the most common type of heart valve ailment
- 30-day early feasibility study results for Cephea will be presented at TCT 2026

ABBOTT PARK, Ill., Oct. 29, 2026 /PRNewswire/ -- Abbott (NYSE: ABT), the global healthcare leader, announced today it has initiated the CROWN-MV pivotal trial evaluating the safety and effectiveness of its investigational Cephea™ Mitral Valve System in treating people with symptomatic mitral valve disease who are not candidates for surgery and transcatheter repair. The first enrollment in the CROWN-MV study occurred at Ascension Via Christi Hospital in Wichita, Kan., led by Bassem Chehab, M.D.

The prospective study will enroll up to 585 people in the U.S., Canada and Europe diagnosed with either moderate-to-severe or severe mitral regurgitation (MR, or a leaky mitral valve) or mitral valves that are not functioning properly due to a buildup of calcium in the base of the valves (known as mitral annular calcification, or MAC).

"Patients with severe symptomatic mitral valve disease often cannot undergo conventional surgery or transcatheter mitral valve repair, and therapeutic options for these patients have been extremely limited," said Juan F. Granada, M.D., president and chief executive officer of the Cardiovascular Research Foundation (CRF) and CROWN-MV trial chair. "The initiation of the CROWN-MV trial represents an important step forward in bringing a dedicated single-step catheter-based replacement option to clinical practice for these high-risk patients. Designed to treat complex mitral anatomies, Cephea has the potential to address a significant unmet patient need."

Expanding treatment options for mitral valve disease
Mitral valve disease occurs when the heart's mitral valve does not function properly. It comes in two forms: regurgitation, a condition where blood leaks backward through the heart, or stenosis, a narrowing of the valve which restricts blood flow through the heart.

For patients who are not candidates for mitral valve repair or open-heart surgery, the Cephea system offers an alternative minimally invasive way to replace the valve. The Cephea device is delivered by catheter through a vein in the leg, where it is guided across the wall between the chambers of the heart. The bioprosthetic (tissue) valve is implanted and expanded inside the diseased mitral valve to restore normal blood flow. The investigational Cephea system is designed to complement Abbott's mitral valve portfolio that includes MitraClip™, the world's first minimally invasive transcatheter edge-to-edge repair (TEER) therapy (which clips the leaflets of the mitral valve together), and the first-of-its-kind Tendyne™ transcatheter mitral valve replacement (TMVR) system (which delivers a self-expanding valve through a small incision in the chest).

Data support Cephea's third-generation delivery technology

During an Innovation Session at the 38th Transcatheter Cardiovascular Therapeutics (TCT) annual scientific symposium of the Cardiovascular Research Foundation in San Diego (October 31-November 3, 2026), researchers will present the first 30-day early feasibility study outcomes for patients treated with the third-generation Cephea delivery system. The data presented on Sunday, Nov. 1 at 2:57 p.m. PT will further demonstrate the device's performance in reducing MR and improving quality of life.

"With Abbott's first-of-its-kind MitraClip, we were pioneers in offering a minimally invasive therapy to treat mitral regurgitation. Building on more than two decades of mitral valve leadership, Cephea is one example of how Abbott continues to innovate to address the diverse needs of patients with mitral valve disease," said Sandra Lesenfants, senior vice president of Abbott's structural heart business. "Early clinical experience with Cephea and the launch of the CROWN-MV pivotal trial underscore the potential of this technology and move us closer to understanding how it may benefit patients with mitral valve disease."

Other results highlighting Abbott's heart therapies
Data will be presented at TCT 2026 on a number of Abbott's cardiovascular devices, including:

- Late-breaking one-year outcomes from the VERITAS Study of the Amulet 360™ Left Atrial Appendage Occluder (Sunday, Nov. 1, 3:09 p.m. PT)
- Thirty-day results from the TECTONIC Coronary Artery Disease (CAD) Intravascular Lithotripsy (IVL) trial of the SonicForce™ Coronary IVL System (Sunday, Nov. 1, 12:44 p.m. PT)
- The first report of six-month clinical outcomes from the early feasibility study for the investigational Encantor™ transcatheter aortic valve implantation (TAVI) balloon-expandable system (Sunday, Nov. 1, 11:13 a.m. PT)
- Thirty-day results from the PARADIGM trial that supported the recent FDA approval for the Amplatzer™ Paraclose PVL Occluder (Saturday, Oct. 31, 9 a.m. PT)
- Five-year outcomes from the IDE study for the Navitor™ TAVI system (Monday, Nov. 2, 3:30 p.m. PT)

Frequently Asked Questions:
What is symptomatic mitral valve disease (MVD)?
Mitral valve disease occurs when the heart's mitral valve does not function properly, leading to either blood leaking backward into the lungs (mitral regurgitation) or restricted flow (mitral stenosis). If left untreated, severe MVD forces the heart to work harder, which can cause symptoms like shortness of breath and chronic fatigue, and eventually lead to heart failure hospitalizations and premature death.

How does Abbott's Cephea work?
Abbott's investigational Cephea Mitral Valve System is implanted through a catheter that is inserted through a vein in the leg and then guided to the heart. The bioprosthetic (tissue) valve is then positioned to replace the diseased mitral valve to restore normal blood flow through the heart.

How does transcatheter mitral valve replacement differ from repair?
Transcatheter edge-to-edge repair systems, including Abbott's MitraClip, work by clipping together a portion of the leaflets of the mitral valve together to reduce the backflow of blood. Transcatheter mitral valve replacement (TMVR) replaces the native valve with a bioprosthetic (tissue) valve, delivered either through a vein in the leg (such as with Abbott's Cephea Mitral Valve System) or through a small incision in the chest (such as with Abbott's Tendyne TMVR system). TMVR may offer an option for patients with extensive calcium buildup or damaged mitral valve leaflets who cannot be treated with repair.

What is the CROWN-MV clinical trial?
CROWN-MV is Abbott's global, prospective pivotal clinical study to assess the safety and effectiveness of the Cephea system in treating severe mitral regurgitation and mitral valve dysfunction associated with mitral annular calcification (MAC). The study will enroll up to 585 people in the U.S., Canada and Europe.

Cephea, Encantor, Amulet 360 and SonicForce Coronary IVL System remain investigational use only in the U.S.

For U.S. important safety information on MitraClip, visit https://abbo.tt/MitraClipISI.

For U.S. important safety information on Tendyne, visit https://abbo.tt/TendyneISI.

About Abbott:
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