NEWS RELEASE

FDA Approves Edwards Lifesciences' SAPIEN M3 Mitral Valve Replacement System as First Transseptal Transcatheter Therapy

2025-12-23

IRVINE, Calif.--(BUSINESS WIRE)-- Edwards Lifesciences (NYSE: EW) today announced the company’s SAPIEN M3 mitral valve replacement system is the first transcatheter therapy utilizing a transseptal approach to receive U.S. Food and Drug Administration (FDA) approval for the treatment of mitral regurgitation (MR). The SAPIEN M3 transcatheter mitral valve replacement (TMVR) system is indicated for the treatment of symptomatic moderate-to-severe or severe MR in patients who are deemed unsuitable for surgery or transcatheter edge-to-edge repair (TEER) therapy by a multidisciplinary heart team. It is also indicated for the treatment of symptomatic mitral valve dysfunction (moderate-to-severe or severe MR, severe mitral stenosis (MS), or moderate MR with moderate MS) associated with mitral annular calcification (MAC) in patients who are deemed unsuitable for surgery or TEER therapy by a multidisciplinary heart team.

Edwards Lifesciences' SAPIEN M3 Transcatheter Mitral Valve Replacement System

“Mitral regurgitation is very common among valvular heart

diseases, and these patients often present with debilitating symptoms that are life-threatening and significantly diminish their quality-of-life. Up to this point, many patients were unsuitable for available treatment options, leaving the vast majority untreated and suffering," said David Daniels, M.D., Sutter West Bay Medical Group cardiologist and structural heart section chief of Sutter's Heart & Vascular Service Line. "The SAPIEN M3 system's ability to provide a fully percutaneous mitral valve replacement that safely delivers near elimination of significant mitral regurgitation and meaningfully improves their symptoms is a game-changer for these patients."

The SAPIEN M3 TMVR procedure involves two steps: dock delivery followed by valve delivery, completely replacing the mitral valve. Both the dock and the valve are delivered through a percutaneous, 29F outer diameter steerable guide sheath inserted through the femoral vein.

One-year data from the ENCIRCLE single-arm pivotal trial was presented at TCT on October 27, 2025, and was simultaneously published in The Lancet. The trial achieved all primary and secondary endpoints for safety and effectiveness in the trial's main cohort (299 patients unsuitable for other treatment options), achieving significant MR elimination (95.7% MR ≤ 0/1+) and meaningful improvements in symptoms and quality-of-life.

"Over our more than 65-year history, Edwards has continued to push the boundaries of structural heart innovation, and today, with the addition of mitral replacement to our portfolio of FDA-approved transcatheter therapies that already includes mitral repair, we are expanding the treatable patient population in the US," said Daveen Chopra, Edwards' corporate vice president, transcatheter mitral and tricuspid therapies. "Edwards is once again transforming care for patients with the SAPIEN M3 system, which is built on the foundation of the proven SAPIEN platform and is supported by positive one-year ENCIRCLE pivotal trial data."

The SAPIEN M3 system received CE Mark in April 2025, making it the world's first approved transfemoral transcatheter mitral valve replacement system. Edwards' portfolio of FDA-approved transcatheter mitral and tricuspid therapies includes the PASCAL Precision mitral valve repair system and the EVOQUE tricuspid valve replacement system.

About Edwards Lifesciences

Edwards Lifesciences is the leading global structural heart innovation company, driven by a passion to improve patient lives. Through breakthrough technologies, world-class evidence and partnerships with clinicians and healthcare stakeholders, our employees are inspired by our patient-focused culture to deliver life-changing innovations to those who need them most. Discover more at **www.edwards.com** and follow us on LinkedIn, Facebook, Instagram and YouTube.

This news release includes forward-looking statements within the meaning of Section 27A of the Securities Act of

1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, but are not limited to, statements made by Mr. Chopra and statements regarding expected product benefits, including near elimination of significant mitral regurgitation, improvement of symptoms, transforming care for patients and other statements that are not historical facts. Forward-looking statements are based on estimates and assumptions made by management of the company and are believed to be reasonable, though they are inherently uncertain and difficult to predict. Our forward-looking statements speak only as of the date on which they are made, and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause results to differ materially from those expressed or implied by the forward-looking statements based on a number of factors as detailed in the company's filings with the Securities and Exchange Commission. These filings, along with important safety information about our products, may be found at Edwards.com.

Media Contact: Loree Bowen, 714-403-2475
Investor Contact: Mark Wilterding, 949-250-6826

Source: Edwards Lifesciences Corporation