PRESS RELEASE

HighLife Receives CE Mark Approval for Clarity Valve, the Next-Generation Valve for the HighLife TMVR System

Paris, France - August 27, 2026 – HighLife SAS, a medical technology company focused on the development of a unique transcatheter mitral valve replacement ("TMVR") system to treat patients suffering from mitral regurgitation, today announced CE Mark approval for the HighLife Clarity Mitral Heart Valve for use with the HighLife Transcatheter Mitral Valve Replacement (TMVR) System.

The Clarity Valve represents the next-generation evolution of the HighLife TMVR platform, purpose-built to further mitigate left ventricular outflow tract obstruction (LVOTO)-related anatomical concerns while preserving HighLife's established transfemoral valve-in-ring architecture.

The approval covers both Clarity Valve Sizes – the HighLife standard Clarity Valve and the HighLife LAV Clarity Valve, maintaining the HighLife TMVR System's ability to treat a native mitral annulus range of 30–53 mm — the broadest range of any CE Mark–approved TMVR system. *

The Clarity Valve is approved for use in adult patients with symptomatic moderate-severe or severe mitral valve regurgitation (MR), who are deemed unsuitable for surgical repair or replacement and transcatheter edge-to-edge repair by a multidisciplinary heart team.

The CE Mark approval of the Clarity Valve builds on the initial CE Mark approval of the HighLife TMVR System announced in January 2026.

Purpose-Built to Address a Critical TMVR Barrier

LVOTO risk remains one of the most important anatomical challenges in TMVR. In many patients, projected neo-LVOT area is a key determinant of anatomical suitability, and concerns regarding LVOTO can contribute to screen failure even when patients otherwise have a significant unmet clinical need.

The Clarity Valve was developed specifically to address this challenge. By reducing material coverage in the outflow portion of the valve frame, the Clarity Valve is designed to allow blood flow through the valve frame toward the LVOT, while preserving the HighLife valve-in-ring architecture, sub-annular fixation concept, and transfemoral procedural approach.

Clinical experience with the Clarity Valve has included evaluation of LVOT performance over follow-up in the Clarity cohort, including independent core-lab assessment of LVOT gradients and evaluation of the potential impact of left ventricular reverse remodeling on neo-LVOT anatomy. These data provide clinical context for the Clarity open-cell design and its intended role in addressing LVOTO-related anatomical concerns.

"LVOTO risk is one of the central anatomical concerns in transcatheter mitral valve replacement and an important driver of patient screen failure," said Professor Michael Joner, Deutsches Herzzentrum München. "The Clarity Valve was purpose-built to address this concern through an open-cell outflow design that preserves a pathway for blood flow toward

the LVOT. In the clinical experience presented to date, we observed no LVOT obstruction at 30 days or 1 year, including in patients with substantial reverse remodeling and very small neo-LVOT areas."

Built on Durable HighLife Platform Performance

The Clarity Valve builds on longer-term clinical experience with the HighLife TMVR platform. Four-year follow-up data from the first 35 consecutively treated patients demonstrated durable valve-related performance, including sustained reduction of MR, stable mean valve gradients, no reported clinical valve thrombosis, no reported LVOT obstruction, no reported hemolysis, and no reported percutaneous PVL closure.

Mean HighLife valve gradients remained low and stable through 4 years, with a reported mean gradient of 4.7 mmHg at 4-year follow-up. The four-year dataset also showed limited incremental heart failure hospitalizations between 2 and 4 years, with no increase in conversion to surgery or reintervention after 1 year.

"The Clarity Valve represents an important evolution of the HighLife TMVR platform," said Stefan Pilz, Chief Executive Officer of HighLife. "With CE Mark approval, we can continue our phased commercial introduction in Europe with a next-generation valve designed around one of the most important barriers to TMVR adoption: anatomical suitability related to LVOTO risk. Our goal remains to bring a differentiated transfemoral mitral valve replacement option to patients with limited treatment options, while maintaining a disciplined, evidence-driven commercial rollout."

Supporting Future Evidence Generation

The Clarity Valve is also the planned study device for HighLife's U.S. pivotal trial, which is expected to begin enrolling and treating patients in Q3 2026.

"The Clarity Valve is highly relevant to the future of TMVR because it focuses on one of the key challenges physicians face when evaluating patients for mitral valve replacement: whether the anatomy can be treated safely and predictably," said Thomas Waggoner, DO, Co-Principal Investigator of the HighLife U.S. pivotal trial. "As the study device for the U.S. pivotal trial, Clarity will allow us to evaluate the HighLife platform in a broader clinical population while generating important evidence for patients with severe mitral regurgitation who are not candidates for surgery or repair."

About Mitral Regurgitation

Mitral regurgitation is one of the most common forms of heart valve disease and occurs when the mitral valve does not close properly, allowing blood to leak backward into the left atrium. Patients with significant MR may experience shortness of breath, fatigue, reduced exercise capacity, recurrent heart failure hospitalizations, and increased mortality risk. Many patients with significant MR are not candidates for surgery or transcatheter edge-to-edge repair due to clinical risk, anatomy, or other patient-specific factors.

About the HighLife TMVR System

The HighLife TMVR System is a transfemoral transcatheter mitral valve replacement system designed to treat patients with significant mitral regurgitation who are unsuitable for surgery or transcatheter edge-to-edge repair. The system uses a dual-component valve-in-ring architecture, with a sub-annular ring designed to support anchoring and sealing of the

transcatheter mitral valve. The HighLife approach is designed to fit naturally within the cath-lab workflow and provide physicians with a reproducible transfemoral TMVR option for appropriately selected patients.

The Clarity Valve is the next-generation valve for the HighLife TMVR System. Its open-cell outflow design is intended to further mitigate LVOTO-related anatomical concerns while preserving the established HighLife valve-in-ring architecture.

Availability Notice

The HighLife TMVR System, including the Clarity Valve, has received CE Mark approval and is being introduced through a limited market release in select European regions. The HighLife TMVR System, including the Clarity Valve, is not available for sale in all countries or regions.

The HighLife TMVR System, including the Clarity Valve, is not approved or available for commercial sale in the United States and is limited to investigational use in the U.S. under applicable regulatory approvals.

*Based on publicly available sizing information for CE Mark–approved transcatheter mitral valve replacement systems.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the expected commercial introduction of the Clarity Valve, the planned U.S. pivotal trial, anticipated enrollment and treatment timelines, future clinical evidence generation, and the potential benefits of the HighLife TMVR System and Clarity Valve. These statements are based on current expectations and are subject to risks and uncertainties that could cause actual results to differ materially. HighLife undertakes no obligation to update any forward-looking statements except as required by applicable law.

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