PRESS RELEASE

HighLife Receives CE Mark Approval for its TMVR Solution

Paris, January 26, 2026 – **HighLife** SAS, a leading MedTech company focused on transcatheter solutions for structural heart disease, today announced that it has received **CE Mark approval** for the HighLife Transcatheter Mitral Valve Replacement (TMVR) System for the treatment of adult patients suffering from symptomatic moderate-severe or severe mitral valve regurgitation (MR), who are deemed unsuitable for surgical repair/replacement and transcatheter edge-to-edge repair by a multi-disciplinary heart team.

The initial commercial availability of the HighLife TMVR system across Europe provides access to a transfemoral mitral valve replacement option featuring a dual-component valve-in-ring design, capable of treating the broadest range of native mitral annulus sizes (30–53 mm) of any CE Mark–approved TMVR system*.

Durable Valve Performance and Meaningful Patient Benefit

Clinical experience with the HighLife TMVR system includes patients treated across multiple countries, with longer-term follow-up data demonstrating durable outcomes, including:

- Sustained reduction of mitral regurgitation to mild or less

- Durable annular sealing enabled by HighLife's sub-annular ring fixation design, with no reported peri- or post-procedural PVL closure

- No reported cases of clinically significant hemolysis or clinical valve thrombosis

- No reported cases of left ventricular outflow tract obstruction (LVOTO)

- Evidence of left ventricular reverse remodeling

- Improvements in NYHA functional status and quality of life, including clinically meaningful changes in KCCQ and 6MWT

"Long-term durability data in TMVR are extremely limited, which is why the HighLife clinical experience is particularly meaningful," said **Professor Wolfgang Rottbauer, Universitätsklinikum Ulm**. *"The system has demonstrated stable performance over multiple years, together with a transfemoral approach and predictable valve function, offering physicians an important new option for patients with severe mitral regurgitation who are not candidates for surgery or repair."*

Supporting Physician Adoption and Clinical Confidence

HighLife has placed a strong emphasis on procedural reproducibility and imaging-based follow-up to support safe and consistent adoption as the therapy transitions into early commercial use, reinforcing confidence in real-world clinical practice.

"HighLife offers a procedural approach that feels familiar to interventional teams," said **Professor Michael Joner, Deutsches Herzzentrum München**. *"The two-step process of ring implantation followed by valve deployment is straightforward and reproducible, fits naturally into the cath-lab*

environment, and can be performed within procedure times similar to those of transcatheter edge-to-edge repair."

European Commercial Rollout

With CE Mark approval, HighLife will begin a phased commercial introduction across Europe, working closely with experienced structural heart centers to support initial cases, physician training, and post-market clinical follow-up.

"CE Mark approval allows us to begin the next phase of HighLife's journey—bringing a new transcatheter mitral valve replacement option to patients in Europe, particularly those with limited treatment options today," said **Stefan Pilz, Chief Executive Officer of HighLife.** *"Each year, an estimated 300,000 patients in Europe with mitral regurgitation are not treated with heart surgery or transcatheter repair, and we are thrilled to offer this population a new treatment option. We are committed to a thoughtful commercial introduction, working closely with leading heart centers to ensure high-quality outcomes."*

The company plans to continue expanding its clinical evidence base, including longer-term durability follow-up and additional publications in peer-reviewed journals and leading cardiology congresses.

For more information about the HighLife TMVR system, please visit: https://www.highlifemedical.com/our-tsmvr-solution/

About HighLife

HighLife is a medical device company dedicated to advancing transcatheter solutions for structural heart disease. The company's TMVR system is designed to provide a transfemoral, durable, and anatomically versatile replacement option for patients with severe mitral regurgitation who are underserved by existing therapies.

Founded in 2010 and headquartered in Paris, HighLife also operates a U.S. facility in Irvine, California, and works in close collaboration with leading physicians and clinical centers worldwide.

HighLife is backed by international investors: Sofinnova Partners, Andera Partners, VI Partners, USVP and Sectoral Asset Management.

**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 related to product availability, clinical development, and commercialization plans. Actual results may differ due to regulatory, clinical, or market factors.

PRESS RELEASE

Availability Notice

The HighLife TMVR System has received CE Mark approval and is not available for sale in all countries or regions. The HighLife TMVR system 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.

Media & Investor Inquiries

HighLife Medical
Amina Benkabou: abenkabou@highlifemed.com
Tel: +33 (0)1 72 32 21 25
www.highlifemedical.com