



PRESS RELEASE

HighLife Raises \$90+ Million to start its US Pivotal Study and accelerate Commercial Expansion in Europe

Paris, France, September 22 – HighLife SAS, a MedTech company focused on transcatheter solutions for structural heart disease, today announced **the successful completion of a \$90+ Million (€80 Million) financing round**. The fundraise was co-led by Andera Partners, Sofinnova Partners, Supernova Invest and Mérieux Equity Partners. Other new investors also joined the round, including the European Investment Bank, BNP Paribas Développement, Capricorn Partners, Critical Path Ventures, Pro Benefis Familiae, SPRIM Global Investments Ltd. and a global strategic alongside existing investors USVP, Sectoral and VI Partners, who participated in the round. The capital will accelerate HighLife's commercial expansion across Europe and advance its US clinical development program.

HighLife has achieved significant regulatory and clinical milestones this year. In January, the company received CE Mark approval for its Transcatheter Mitral Valve Replacement (TMVR) system, enabling the start of a limited market release in Europe while also initiating its US pivotal clinical study. In July, HighLife received CE Mark approval for the Clarity Valve, HighLife's next-generation valve, purpose-built to further mitigate LVOT obstruction risk, the primary barrier to adoption for TMVR. Together these milestones strengthen HighLife's ability to expand treatment access for patients who have limited therapeutic options.

*"This financing represents an important milestone as HighLife continues to build momentum toward establishing its technology as a new treatment option for patients suffering from mitral regurgitation who have limited therapeutic alternatives. It will support HighLife's strategic roadmap, by accelerating commercial expansion across Europe, advancing its pivotal clinical study and strengthening the organization to support long-term growth", said **Stefan Pilz, Chief Executive Officer of HighLife**.*

*"We believe transcatheter mitral valve replacement is reaching a critical inflection point. With differentiated technology, a highly experienced team and a strong financial foundation, we believe HighLife is particularly well positioned to establish itself as a global leader in this new therapeutic approach." said **Rémi Spagnol, Partner Supernova Invest**, co-lead investor in the round.*

*"The strength of this financing reflects strong investor confidence in the leadership of the company, its strategy and winning technology. HighLife has built a strong foundation, and we believe the company is well positioned to execute its next phase of growth to treat patients who have no other option today." said **Jose ("Pepe") Calle Gordo**, Chairman of the Board.*

The HighLife Transcatheter Mitral Valve Replacement (TMVR) System consists of a valve-in-ring concept, both ring and valve being implanted percutaneously. This concept is mimicking the surgical gold standard (annuloplasty ring + valve). It is intended 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.

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



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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.

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.

Availability Notice

The HighLife TMVR System and Clarity TMVR System have received CE Mark approval and are not available for sale in all countries or regions. These products are not approved or available for commercial sale in the United States, and are limited to investigational use in the U.S. under applicable regulatory approvals.

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