



PRESS RELEASE

HighLife launches a new Large Annulus Valve in ongoing clinical studies for patients suffering from Mitral Regurgitation

First patients successfully treated with the new Large Annulus Valve

Paris, September 06, 2023 - HighLife SAS, a medtech company focused on the development of a novel Trans-Septal Mitral Valve Replacement ("TSMVR") system to treat patients suffering from moderate to severe mitral regurgitation (MR), announced today the introduction of a new valve size in its clinical trials, the Large Annulus Valve (LAV), designed for patients with larger anatomies.

Among patients with moderate to severe MR, there has been a lack of treatment options for patients with large annuli. The new LAV is specifically designed to fit within HighLife's existing delivery catheter and can accommodate large annuli up to 53mm. The LAV is expected to significantly expand the patient population eligible for TSMVR and provide a much needed treatment option to the company's physician partners.

The first LAVs were implanted in the USA. *"We are proud to be the first center in the world to implant the LAV. The outcome obtained is very positive with elimination of MR immediately post-procedure. The patient was discharged home only one day after the procedure and is doing very well since."* states **Dr Thomas Waggoner, Structural Interventional Cardiologist, Director of Structural Heart and Director of Cardiovascular Research - Tucson Medical Center** (Arizona, USA). *"HighLife's solution and this new valve size are a game-changer for our patients with Mitral Regurgitation. This aligns with our vision to improve the well-being and lives for all patients. We look forward to enroll and treat more patients in HighLife's clinical study!"*

"We are excited to launch the Large Annulus Valve. Addressing the unmet needs of patients with moderate to severe MR has been our focus and we are pleased to see that our efforts are enabling access to more patients in our clinical trials. This is an important milestone as we are preparing for our future pivotal study in the USA." concludes **Georg Börtlein, Founder and Chief Executive Officer of HighLife**.

The LAV is available in both the full-coverage and Clarity configurations. HighLife's Clarity valves are specifically intended for patients with a risk for LVOT (Left Ventricular Outflow Tract) obstruction. The LAV is under investigation in clinical studies in the USA, France, Belgium, Germany and Australia and has been submitted for inclusion in ongoing studies in other geographies.

About HighLife

HighLife SAS, headquartered in Paris, France, with facilities in Irvine, California, is a pre-commercial stage company. It is focused on the development of a novel transcatheter replacement system for treating mitral regurgitation.



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The TSMVR solution developed by HighLife consists of a valve-in-ring concept, both ring and valve being implanted percutaneously. The technology is implanted in a simple, 3-step procedure. The valve is deployed in a beating heart, reducing trauma to the patients. It is currently evaluated in clinical studies across three continents.

For more information, visit <https://www.highlifemedical.com/>

Caution: The HighLife Valves are investigational devices and not for sale in any geography.

About Mitral Regurgitation

Mitral Regurgitation is a growing public health concern, affecting over 2% of the total population¹. It refers to a condition in which the valve between the heart's left chambers (the mitral valve) does not close completely, allowing blood to leak back across it, rather than continuing to supply the organs with oxygenated blood. Without proper treatment, severe Mitral Regurgitation can cause major heart problems or even lead to heart failure. Limited treatment options are available for many patients at high surgical risk, TSMVR solutions offer a less invasive alternative to traditional open-heart surgery.

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¹Burden of valvular heart diseases: a population base study. Nkomo VT et al.