PRESS RELEASE

HighLife Receives IDE Approval to Initiate US Pivotal Clinical Study for treatment of Mitral Regurgitation

Paris, June 3rd 2024 - 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 that the U.S. Food and Drug Administration (FDA) granted an Investigational Device Exemption (IDE) to initiate a US Pivotal Study with its technology.

The Pivotal Study is a single-arm, multicenter, prospective study assessing the safety and effectiveness of the HighLife TSMVR solution in patients with moderate to severe Functional Mitral Regurgitation (FMR), unsuitable for surgery or transcatheter repair treatment. This patient population lacks approved therapeutic options, leading to a poor prognosis with many recurrent hospitalizations and reduced life expectancy.

The pivotal study is expected to enroll patients at clinical sites in the United States, Europe and APAC.

Over 100 patients have been treated with the HighLife technology within different clinical programs in the USA, Europe and APAC. Study results have been presented at conferences globally and published in JACC (Journal of the American College of Cardiology) - Cardiovascular Interventions[1].

Prof. Gregg W. Stone, Director of Academic Affairs for the Mount Sinai Health System and Professor of Medicine (Cardiology), and Population Health Science and Policy, at the Icahn School of Medicine at Mount Sinai (New York, USA) will be the Principal Investigator of the Pivotal study. *"I am honored to lead the HighLife pivotal study. There is still a significant unmet clinical need for patients suffering from mitral regurgitation and TMVR is a promising treatment option. The HighLife TMVR solution offers the potential to provide important clinical benefits for these high-risk patients. We are gratified that FDA has granted approval for this pivotal study that will further advance the management of patients with MR"* commented Prof. Stone.

Georg Börtlein, Founder and Chief Executive Officer of HighLife, said, *"We are extremely pleased with the FDA IDE approval for our US pivotal study, marking a significant milestone in our US clinical strategy. This approval aligns with the maturity of our extensive clinical dataset generated over multiple sites across three continents. We are also making great progress towards CE mark readiness, eagerly anticipating the market introduction of our technology in Europe."*

The HighLife technology will be featured at NY Valves annual meeting on Thursday, June 6th at 11am in the session "Innovation at NYV: Transfemoral TMVR - Technology and Clinical Updates" - Room: Innovation & FDA, 504, Level 5, Jacob K. Javits Convention Center, North.

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[1] 1-Year Outcomes Following Transfemoral Transseptal Transcatheter Mitral Valve Replacement: The HighLife TSMVR Feasibility Study. J Am Coll Cardiol Intv. 2023 Dec, 16 (23) 2854–2865

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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.

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 population[2]. 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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[2]Burden of valvular heart diseases: a population base study. Nkomo VT et al.