PRESS RELEASE

HighLife Receives ISO 13485 Certification of its Quality Management System

Paris, August 27 2024 - HighLife SAS, a medtech company focused on the development of a novel Trans-septal Mitral Valve Replacement ("TMVR") system to treat patients suffering from moderate to severe Mitral Regurgitation (MR), announces today that it has received EN ISO 13485:2016 certification of its quality management system for its Paris, France and Irvine, California locations.

ISO 13485, established by the International Standards Organization (ISO), is a globally recognized standard that provides the quality management system requirements, essential for medical device reliability, procedure efficacy, and patient safety. The standard applies to the entirety of a product's lifecycle, from conceptual design through commercialization and is required to gain access to international markets. Obtaining this certification indicates that a company has established robust policies and procedures for the development and commercialization of regulated medical products. The scope of this certification includes design, development, manufacture, and distribution of prosthetic implantable heart valves, sub-annular implants, accompanying delivery catheters, and valve loading devices for the clinical application of mitral valve replacement.

Stefan Pilz, Chief Executive Officer of HighLife, said "*We are very proud to receive the ISO 13485 certification. Quality is the cornerstone of our organization: Obtaining this important ISO standard demonstrates our commitment to reaching the highest standards of quality and to meeting international regulatory requirements, paving the way for regulatory approvals and market introduction of our TMVR technology.*"

The EN ISO 13485:2016 certification was granted by DEKRA, one of the world's largest independent expert organization in the field of testing, inspection and certification.

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 TMVR 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.

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

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

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

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About Mitral Regurgitation

Mitral Regurgitation is a growing public health concern, affecting over 2% of the total population[1]. 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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[1] Burden of valvular heart diseases: a population base study. Nkomo VT et al.