Transcatheter Mitral Valve Implantation

Press Release

HIGHLIFE SUCCESSFULLY INITIATES ITS CLINICAL STUDY IN EUROPE

First 3 activated clinical centers in France enroll patients

PARIS, France, September 22, 2017 – HighLife SAS announced today the start of its European clinical study with the enrollment of **the first 3 patients** at major French university hospitals.

This study is a non-randomized, multicenter, prospective clinical study targeting to enroll up to twenty patients in Europe. It has been approved by the French competent authority ANSM earlier this year. It is targeting treatment of patients with severe mitral regurgitation not eligible for surgical valve repair/replacement according to multidisciplinary Heart Team decisions. The study is evaluating the company's technology using a trans-apical access, namely by a delivery of the bioprosthetic valve through a puncture at the patient's tip of the heart. It is conducted in collaboration with the Action Study Group (www.action-coeur.org).

The first case was carried out at the **University Hospital in Toulouse** by Bertrand Marcheix, MD, PhD, professor of cardiac surgery and Thibault Lhermusier MD, PhD interventional cardiologist. The second case was performed by Jean-Philippe Collet MD, PhD, professor of cardiology and Pascal Leprince, MD, PhD, professor of cardiac surgery at **Hospital Pitié-Salpêtrière in Paris**. The third case was carried out at the **University Hospital in Rennes** by Hervé Le Breton, MD, PhD, professor of cardiology, Guillaume Leurent, MD, PhD, interventional cardiologist and Hervé Corbineau, MD, PhD, professor of cardiac surgery.

All procedures were carried out as planned, and the HighLife bioprosthesis was adequately implanted in all three cases. "The very innovative HighLife approach enables a well-controlled stepwise procedure." said **Jean-Philippe Collet**, Principal Investigator of the study, "After these first three cases, all current centers are looking forward to treating more patients with otherwise limited therapeutic options."

The clinical cases were done with the assistance of **Nicolo Piazza** MD, PhD, FRCPC, FESC interventional cardiologist at McGill University Health Center in Montreal (Canada) and **Ruediger Lange** MD, PhD, head of cardiac surgery in the German Hear Center in Munich (Germany) whose contributions and guidance have been instrumental in the development of the technology.

"We are very happy about the start of this multicenter clinical experience in our European study, which show that the innovative HighLife technology can be used by multiple Heart Teams. We look forward to extending the study to more clinical centers." said **Georg Börtlein**, Founder and Chief Executive Officer of HighLife "This early European experience tends to confirm the positive results generated in our first-in-man experience carried out last year in Ukraine and Italy".

Upcoming presentations

The technology and long term clinical data obtained with the HighLife technology will be presented at the following upcoming major scientific meetings : London Valves 2017 on September 25, 2017 by Prof. Ruediger Lange, EACTS in Vienna on October 7, 2017 by Prof. Ruediger Lange, TCT 2017 in Denver on October 31, 2017 by Dr Nicolo Piazza.

The HighLife technology relies on the initial placement of a ring component around the native mitral leaflets in a reversible manner. Once this first component's position is confirmed, the bioprosthesis can be delivered within minutes through the ring and in position inside the native annulus.

About HighLife
HighLife SAS, headquartered in Paris, France, with offices in Irvine, California, is an early-stage company established in 2010. It is focused on the development of a novel transcatheter replacement system for treating mitral regurgitation. The technology aims at a beating heart procedure reducing trauma to the patients.
The HighLife Transcatheter Mitral Valve is an investigational device, not available for sale.

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