

Very positive results one month after Epygon mitral heart valve implantation in a first patient

- **Very positive outcome at one month follow-up of the patient implanted with the Epygon mitral valve.**
- **Validation by the Independent Safety and Monitoring Board of the data to continue the Minerva pilot study.**
- **Several patients already identified in investigational clinical centers in Europe to move forward in the clinical trial.**

Aix-en-Provence, April 17, 2023 - 5:30 pm CET- Affluent Medical (ISIN code: FR0013333077 – ticker: AFME), a French MedTech specializing in the international development and industrialization of innovative medical prostheses, at a clinical stage, to treat mitral heart valve pathology and urinary incontinence, announced today **very positive one-month follow-up results of the patient** implanted last February **with a minimally invasive transcatheter Epygon biomimetic mitral valve** in the Minerva pilot clinical study.

This first successful implantation was performed by Prof. Stefano Salizzoni, MD, PhD - co-investigator of the study - and his team, at the Molinette Hospital of Health and Science in Turin, Italy.

The implanted patient had a severe mitral insufficiency profile associated with comorbidities: severe diabetes, severe tricuspid regurgitation with a pacemaker, and ischemic heart disease, with risk of infarction. She benefited from a transcatheter implantation, avoiding an open-heart procedure, with a 15-minute valve positioning time and a short stay in intensive care. She was promptly discharged from the hospital for cardiac rehabilitation at D+5 after the procedure.

Her health status changed **very quickly in a positive way. After one month, she improved her functional status, changing the New York Heart Association (NYHA) functional status from III to II. This mean the patient is able to resume basic day to day activities without being out of breath.** The echocardiography showed excellent function of the Epygon valve.

The **independent Data Safety and Monitoring Board** met on April 7, 2023, to review the case and **confirmed that the ongoing study could continue.**

As such, Affluent Medical **is actively working on planning for the next patients** to expand the study targeting between 10 and 15 patients at different investigational centers in Europe. **To date, at least 5 additional patients have already been identified and will be eligible for Epygon mitral valve implantation in the coming months.**

Mitral insufficiency is a serious and lethal heart disease that affects nearly 2% of the world's population, with an incidence that increases with patient age. Less than 4% of patients with severe heart mitral insufficiency receive surgery, according to Affluent Medical estimates. Without surgery, the risks of death and hospitalization are high, with up to 50% death at 5 years and 90% hospitalization for those patients still alive.

Affluent Medical is developing a minimally invasive transcatheter route for its Epygon valve, which through a small incision in the chest and heart, with a beating heart, allows its new valve to be deployed, which hooks spontaneously, and without sutures between the atrium and left ventricle. **It is the only biomimetic cardiac mitral valve in development, mimicking the native mitral valve and physiological blood flow.**

Sébastien Ladet, CEO of Affluent Medical states: " *We are very pleased with the one-month follow-up results for this first successful implantation in a high-risk patient. This procedure is a major advance for structural cardiology and opens the door to further implantations in patients with severe mitral insufficiency who cannot undergo open heart surgery. We are targeting 10 to 15 implants before the end of 2023 and will report interim results from 5 patients during the EACTS in October 2023.*"



About Epygon valve

Epygon is the first biomimetic transcatheter mitral valve that restores the natural vortex of blood flow in the left ventricle, thereby promoting recovery of ventricular function, particularly in frail patients with severely altered cardiac conditions. It is designed to potentially ensure superior clinical outcomes in patients with severe mitral regurgitation.

The unique features of the device include a single leaflet made of pericardial tissue combined with a D-shaped stent. The asymmetric nitinol stent, with its anatomical anchoring systems, ensures a stable anchoring under the mitral annulus, by capturing the native leaflets and achieving an optimal fit with a low risk of LVOT (left ventricular outflow tract) obstruction. Its transcatheter implantation makes it a rapid and minimally invasive procedure avoiding open heart surgery.

About the Minerva Clinical Study

The Minerva *First in Human* study is a prospective, multicenter, non-randomized, single-arm study of the minimally invasive Epygon medical device for mitral valve regurgitation, being conducted at 9 clinical investigation centers in Italy, Austria, Spain and Serbia. The study will evaluate several dozen patients to implant the Epygon valve in 10 to 15 adult patients with severe mitral regurgitation, with a NYHA functional class III to IV, and an LVEF (ejection fraction) greater than or equal to 30%. These patients, who are evaluated and selected by a multidisciplinary cardiology team, are all at high risk for mitral valve surgery and are therefore eligible for transcatheter procedure.

The objectives of the study are to evaluate the safety and efficacy of Epygon valve implantation at 30 days. Patients will be monitored for 5 years.



About Affluent Medical

Affluent Medical is a French MedTech company, founded by Truffle Capital, with the ambition to become a global leader in the treatment of structural heart diseases, which are the world's leading cause of mortality, and urinary incontinence which currently affects one in four adults.

Affluent Medical develops next-generation, mini-invasive, innovative, adjustable, and biomimetic implants to restore critical physiological functions. The product candidates developed by the Company are currently in preclinical and clinical studies.

Kalios™, the first mitral adjustable annuloplasty ring, should be the first Affluent Medical device to be marketed. Subject to raising the necessary funds to finance its strategy and to positive results from ongoing clinical studies, the Company's ambition is to progressively commercialize its products starting in 2025.

For more information: www.affluentmedical.com

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