PRESS RELEASE

Affluent Medical announces initial success of first clinical implantation of its Epygon mitral heart valve via minimally invasive route

- **A first success aligned with Affluent Medical's roadmap.**
- **Minimally invasive transcatheter implantation on beating heart by Professor Salizzoni in Italy.**
- **Favorable early outcome of the patient's health condition, currently in cardiac rehabilitation.**
- **Epygon is the only biomimetic mitral valve to restore the physiological blood vortex.**
- **Rapid, 15 minutes, valve implantation procedure and early hospital discharge of the patient on day 5.**

Aix-en-Provence, March 9, 2023 - 7:30 am 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, today announced the initial success of the first minimally invasive transcatheter implantation of its biomimetic Epygon heart valve in a patient in Italy as part of the Minerva pilot clinical study.

This first implantation of the Epygon valve as part of the Mirvana pilot study was successfully performed by Prof. Stefano Salizzoni, MD, PhD who is a co-investigator of the study along with his team at the Molinette Hospital of Health and Sciences of Turin in Italy. Importantly, Professor Marco Vola, cardiac surgeon at the HCL of Lyon was present as a surgical "Proctor" for Affluent Medical during the procedure.

The patient's health condition evolved favorably very rapidly. She is now in post-surgery rehabilitation care. The discharge visit showed a very good ultrasound result relating to the Epygon mitral valve function: no obstruction of the flushing chamber of the left ventricle, no regurgitation, no pressure gradient or paravalvular leakage. A follow-up visit is scheduled at one month post-operatively.

Cardiac mitral regurgitation is a severe 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 cardiac mitral regurgitation benefit from surgery, according to Affluent Medical estimates. Without surgery, the risks of death or repeat hospitalization are high, with up to 50% death at 5 years and 90% hospitalization for patients still alive.

Mitral valve replacement is usually done by invasive cardiac surgery with opening of the chest, stopping and opening of the heart, removal of the damaged valve, suturing of a new valve, a procedure reserved for not too old and healthy patients.

Affluent Medical is developing a minimally invasive, transcatheter route for its Epygon valve, which through a small hole in the chest and heart, on a beating heart, allows its new valve to be deployed in about 15 minutes and hooked spontaneously, and with no need for suturing the valve. It is the only *biomimetic* cardiac mitral valve under development, mimicking the native mitral valve function and generating a physiological blood flow. The implanted patient suffered from a severe mitral insufficiency associated with co-morbidities: severe diabetes, severe tricuspid regurgitation with a pacemaker, and suffering from ischemic heart disease, with risk of infarction. She benefited from the transcatheter Epygon valve implantation - avoiding contraindicated major cardiac surgery - with a very short procedure time (fifteen minutes) and a short stay in intensive care. She was rapidly discharged from the hospital for cardiac rehabilitation on Day 5 post- procedure.

Professor Stefano Salizzoni, MD, PhD, Cardiac Surgeon at Molinette Hospital, Città della Salute e della Scienza in Turin - Italy stated: "*We successfully implanted the Epygon valve in a patient with severe mitral regurgitation who could not be treated by open heart surgery due to numerous comorbidities. The team and I were very impressed with the ease and smoothness of the transcatheter implantation procedure, which avoids open heart surgery. From initial hands-on the Epygon transcatheter device to deploying the valve inside the patient's heart, it took me only 15 minutes. The patient recovered quickly and was discharged from the hospital on day 5. She is now in cardiac functional rehabilitation*."

Professor Marco Vola, Deputy Head of Department and head of the mitral program at the University Department of Adult Cardiac Surgery in Lyon – France, added: "*The implantation of the Epygon transcatheter valve by Prof. Salizzoni was a success. The Epygon valve is inspired by the anatomy of the native mitral valve. It has several unique attributes such as its D-shape, an asymmetrical profile and a single leaflet that aim to preserve the physiological vortex of blood flow. This innovative mitral valve from Affluent Medical benefits from the historical biomedical know-how of the Italian region of Piedmont, with Affluent Medical's development team based in Colleretto, and the strong financial support of its founder and historical investor Truffle Capital that had the merit to fund such a crucial innovation from the beginning.*"

Sébastien Ladet, CEO of Affluent Medical concludes: "*We are very proud of this first successful implantation which represents an important step for the company and structural cardiology. The entire Affluent Medical team and our investigators are delighted with the initial results of this procedure, which confirm the quality of our Epygon medical device and of the medical teams working with us on this pilot study. Obviously, we must remain cautious about these encouraging preliminary results and the need to continue the clinical study before we can conclude on the efficacy and safety in the medium and long term. We are confident that the study will continue and that we will proceed with other implantations in patients suffering from mitral heart regurgitation who are waiting for an innovative therapeutic solution that has no equivalent on the market today.*"

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 implantation of the Epygon valve in 10 to 15 adult patients with severe mitral regurgitation, NYHA functional class III to IV, and 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 a 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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