PRESS RELEASE

Affluent Medical announces positive clinical results and further insights to enhance its strategy on Structural Heart activities

- **Kalios™ adjustable ring for mitral valve repair with positive 1-year results:**
  - Pivotal Optimise II study with 20 patients demonstrated efficacy at 1 year and excellent safety profile
  - Results drove strategic shift to the US market to secure swift pathway to commercialization

- **Initial validations of the potential of Epygon, a transcatheter mitral prosthesis:**
  - Results from first patients treated provide early confirmation of the value of the Epygon valve
  - A survey reveals high value of the Epygon mitral valve perceived by both interventional cardiologists and cardiac surgeons

Aix-en-Provence, September 13th, 2023 – 5:45 pm CEST- Affluent Medical (ISIN code: FR0013333077 – ticker: AFME), a French clinical-stage MedTech company specializing in the international development and industrialization of innovative medical prostheses, today announced positive clinical results from a pivotal study with its mitral ring Kalios™ and insights that support the Company's new strategy regarding its Structural Heart activities.

Kalios™: Positive interim 1-year results from the pivotal Optimise II study with 20 patients

The Company's Kalios™ ring is the only mitral annuloplasty device that can be adjusted percutaneously to treat both residual and recurrent mitral insufficiency at any time after implantation, repeatedly and with a beating heart, thereby avoiding a repeat open-heart operation. The pivotal European Optimise II study with Kalios™ was designed to evaluate the safety and efficacy of the device for the surgical treatment of mitral regurgitation with catheter adjustments.

The results reported today consists of an interim data package of the first 20 patients treated at five centers across Europe at 1 year after implantation. 13 of the patients had primary (degenerative) mitral regurgitation and 7 had functional secondary mitral regurgitation. 5 post-implant adjustments have been performed and one patient was adjusted at 11 months after the surgery. From the 4 patients adjusted peri operatively excellent results were observed (residual mitral regurgitation (MR) grade <2) which have been maintained up to one year.

At 1 year, none of the patients had MR >2+, thus meeting the pre-defined efficacy endpoint of the study.

12 patients had an improvement of the NYHA Functional Class and 79% had a NYHA functional Class I or II. The safety profile of the study was excellent: no death, no myocardial infarction, no valve thrombosis and no endocarditis were reported, up to 1 year.

Prof. Alberto Albertini, M.D., head of the cardiothoracic surgery division at Hesperia Hospital Modena, Italy, explained: *"The results of this interim analysis at 1 year are very exciting. Five patients could be adjusted post-operatively and the outcomes are excellent. Thanks to the catheter adjustment, the mitral regurgitation have been optimized or corrected without an open heart surgery."*

The interim analysis on the primary efficacy endpoint at 1 year of the adjustable mitral ring in the pivotal study will be submitted for publication in a peer-reviewed journal.

Kalios™: Strategic shift to the US market to secure an easier pathway to market launch

As the Company is analysing the positive data at 1 year from the Optimize II pivotal study, it has been decided to refocus the resources on the US market and to rapidly enter in discussions with the US Food and Drug Administration (FDA). The current strategy, only focused on Europe has been carefully re-assessed by the

new management team. Due to the increase of regulatory requirements in Europe (i.e MDR), it is likely the CE path to be more complex and longer than the FDA path. Indeed, the 510K path with the addition of existing clinical data would likely open the US market faster.

While the European market will continue to be an important focus for the Company, the US market offers several advantages beyond being the largest global unified medtech market: On the commercialization side, the average selling price of a mitral ring is 25 to 30% higher compared to the Europe which offers more possibilities for a premium product as Kalios™. In addition, getting approval in the US is well aligned with the Company strategy to secure commercial partners which are mostly located in the US (Medtronic, Boston Scientific, Abbott, Edwards Life science etc..).

The Company is working with several regulatory consultants to reinforce this approach, plans to submit a pre-dossier and subsequently meet the FDA during the next quarter. In parallel, Affluent Medical is also proceeding with a supplier upgrade to strengthen the current supply chain to renew its inventory, prepare the industrialization phase and ensure compatibility with FDA requirements. To optimize expenses the European trial is put on hold during this strategic shift.

Epygon: Increase in patient screening and opening of additional investigation sites

Epygon is the only biomimetic cardiac mitral valve that mimics the anatomy of the native mitral valve and physiological blood flow and can be implanted via a transcatheter route. This transcatheter approach avoids an invasive "open heart" procedure and associated complications to treat cardiac mitral insufficiency.

The clinical pilot study ‘Minerva’ evaluating the minimally invasive Epygon medical device to treat mitral valve regurgitation is currently being conducted in several clinical trial centers. Approval from the DSMB (data safety and monitoring board) allowed the Company to treat additional patients with the Epygon valve.

During the past months, 1 additional center was approved to participate in the clinical trial (Sevilla), bringing the total number of centers to 10. In this context, Affluent Medical accelerated the number of screened patients to reach 80 with the objective to implant up to 10 patients to complete the pilot phase.

Epygon: A survey reveals high value of the Epygon mitral valve perceived by both interventional cardiologists and cardiac surgeons

In June 2023, in-depth interviews were carried out with up to 60 interventional cardiologists (IC) and cardiac surgeons in both US and European Union (EU) to analyse the perception they had of the Epygon mitral valve.

The medical professionals identified several strong value propositions in the Epygon design which will address current unmet needs: hemodynamic profile, anatomical anchorage and a design limiting risks of leakage and obstruction of the LVOT (Left Ventricular Outflow track).

The survey generated very positive responses from both cardiac surgeons and ICs:

- 75% of cardiac surgeons are likely to adopt Epygon in the US and 67% in the EU;
- 70% of IC willing to refer patients to cardiac surgeons if the Epygon was available;
- ICs would refer about 1/3rd of their patients to Epygon, who might benefit from Epygon properties through transapical approach even assuming transeptal valves would be marketed.

The survey highlights that the mitral valve is considered as a high value device for high-risk patients even through a transapical approach because of its unique properties. The Company will continue to validate these survey results as they support its current strategy to continue to develop a transapical version of Epygon while investigating the development of a transeptal version.

As the clinical study is progressing, Affluent Medical recently advanced 2 new valve sizes (40 & 42 size). These 2 additional sizes will accelerate the patient screening while progressively being authorized in additional countries (already approved in Spain and Austria).

About Kalios™

Kalios™ is the only mitral annuloplasty device that can be adjusted percutaneously to treat both residual and recurrent mitral insufficiency at any time after implantation, repeatedly and with a beating heart, thereby

avoiding a repeat open-heart operation. Affluent Medical estimates that Kalios™ would prevent repeat surgery for potentially 30-40% of patients within 5 years. The market for mitral valve repair surgery is estimated to be worth $1.5 billion in the US-Europe region in 2023, growing at 3.5% per year.

About the Optimize II Pivotal Clinical Study

The European Optimise II pivotal study of Kalios™ underway in Europe was designed to evaluate the safety and efficacy of the Kalios™ adjustable ring for the surgical treatment of mitral regurgitation. Patients presenting with primary (degenerative) or secondary (functional) mitral valve regurgitation and candidate for MR repair are included in the study. Up to 100 patients are to be enrolled to obtain 62 evaluable patients at 1 year. Treated patients will be followed during 5 years post surgery.

Primary endpoints are the success rate of annuloplasty surgery defined by absence of MR of grade > 2 and the safety at 1 year.

About Epygon

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 Pilot 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 end of 2025/ early 2026.

For more information: www.affluentmedical.com

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