PRESS RELEASE

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Pivotal study progresses to 24 patients successfully implanted with Kalios™, an adjustable mitral ring that avoids complex re-interventions

- **Excellent results continue to confirm the efficacy of the Kalios™ adjustable mitral ring in the Optimise II pivotal study.**
- **Plenary oral presentation by Prof. Martin Andreas of the results at the EACTS.**
- **Sustained interest from the surgical community, for the Kalios™ adjustable mitral ring function performed on 5 patients.**
- **Engagement of surgeons during the EACTS on the action plans of the clinical studies for Kalios™ and Epygon™.**

Affluent Medical (ISIN code: FR0013333077 - ticker: AFME), a French MedTech specializing in the international development and industrialization of innovative medical devices, at a clinical stage, to treat urinary incontinence and cardiac mitral valve pathologies, announced today that additional results from the Optimize II pivotal study were presented at the EACTS - European Association of Cardio-Thoracic Surgery Congress - in early October, following the follow-up of 8 additional patients.

These additional data were discussed with a community of international cardiac surgery experts by the study investigators.

The Company has also held discussions with the principal investigators of the Optimise II study for Kalios™ and the Minerva study for Epygon™ to accelerate the patient recruitment action plans.

Prof. Martin Andreas, Associate Professor at the Department of Cardiac Surgery of the Medical University of Vienna, presented at the "*Late Breaking Trials*" session at the EACTS congress in Milan, Italy, the interim data of the first 24 patients included in the Optimize II pivotal study.

The major differentiation of Kalios™ is the ability to adjust the size of the ring to reduce residual or recurrent regurgitation.

At this stage of the study five post-implant adjustments were performed because of residual or recurrent grade 3+ to 4+ regurgitation. Four adjustments were performed preoperatively and one adjustment 11 months after implantation. After adjustment, the results in terms of reduction of mitral regurgitation were excellent with for these 5 patients, namely trivial mitral regurgitation (grade 1+). During pre-operative adjustments, the Kalios™ mitral ring has thus made it possible to treat residual leaks at the end of the operation, linked to the choice of the size of the ring to be implanted, by avoiding reconnecting the extracorporeal circulation and reopening the heart. This first adjustment possibility allows an optimal surgical result and a significant time saving during open heart surgery. The adjustment performed at 11 months, allowed the patient to avoid undergoing another long and important open-heart surgery.

Prof. Martin Andreas, Associate Professor at the Department of Cardiac Surgery of the Medical University of Vienna said: "*A few months after the announcement of the first interim results, and as we move forward with the Optimize II study, Kalios™ confirms its position as a highly innovative medical device for the treatment of mitral regurgitation. The results obtained to date, presented in front of a panel of practitioners for the 24 patients implanted, allow us to be very optimistic about the potential of the device to provide a reliable and re-adjustable alternative therapeutic solution for patients suffering from residual or recurrent mitral regurgitation*."

Optimize II is a prospective, single-arm, 5-year study conducted at 10 European centers and was designed to evaluate the safety and efficacy of the Kalios™ device for the surgical treatment of mitral regurgitation with optional intraoperative and/or postoperative non-surgical adjustments. The primary endpoint is the success rate of minimally invasive annuloplasty surgery, defined as the absence of grade[1] > 2 mitral regurgitation at one year.

These 24 patients were recruited from 5 centers (Vienna, Cotignola, Florence, Leipzig, and Passau), half of the patients had primary (degenerative) mitral regurgitation and half had functional secondary mitral regurgitation. The mean age was 66 years and 62.5% of the patients had a functional class NYHA[2] III or IV. The grade of mitral regurgitation was ≥ 3+ in 20 patients.

In half of the cases, patients had concomitant cardiac surgery in addition to the Kalios™ surgical ring. Functional status also improved: more than 80% of patients had NYHA < II at discharge, and these results were maintained up to 6 months.

The safety profile of the study was excellent, no deaths were reported, 4 major cardiac events in 3 patients were observed at 30 days.

About Kalios™

Kalios™ is a patented, adjustable mitral annuloplasty ring that can be adjusted percutaneously to optimize valve repair and treat residual or recurrent regurgitation at any time from the day of implantation.

The Kalios™ technology is designed to allow for targeted and repeatable transcatheter adjustment, optimizing mitral coaptation length after mitral and beating heart repair. The ring adjustment is achieved by introducing a three-position balloon catheter subcutaneously and inflating it to one of the three positions to reduce the ring size by up to 15%. Kalios™ could also improve the long-term treatment of recurrent mitral regurgitation.

About Affluent Medical

Affluent Medical is a French player in MedTech, founded by Truffle Capital, with the ambition of becoming a global leader in the treatment of heart and vascular 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 implants to restore critical physiological functions in these areas. The four major technologies developed by the company are currently in preclinical and clinical studies. Kalios™ is set to be the first medical device to be marketed in Europe.

For more information: www.affluentmedical.com

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[1]Mitral regurgitation grade: Graduation allowing to define the importance of mitral leakage following an ultrasound examination.

[2]NYHA: The NYHA classification is a clinical severity scale for heart failure with diagnostic, prognostic and therapeutic value.