

PRESS RELEASE

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Affluent Medical reports excellent safety and performance interim result of its Optimize II pivotal clinical study with Kalios™, adjustable mitral ring, in the treatment of mitral regurgitation

Affluent Medical (ISIN code: FR001333077 – Ticker: AFME), a French medtech specializing in the international development and industrialisation of innovative medical prostheses, at a clinical stage, to treat cardiac mitral valve pathology and urinary incontinence, today reports excellent safety and performance interim result of its Optimize II pivotal study with Kalios™ adjustable mitral ring.

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

The Kalios™ technology is conceived to allow a targeted and repeated transcatheter adjustment, hence optimizing the mitral coaptation length after mitral repair on beating heart. Ring size adjustment is performed inserting subcutaneously and inflating balloons at one of the three ring position to reduce the size of the ring up to 15%. Kalios™ also would have the potential to improve the longer-term treatment of recurrent mitral regurgitation.

Today we report interim data of the first 16 patients with analysis completed in May 2022 from our pivotal Optimize II study. Optimize II is a prospective, single arm, 5 years study (for safety reporting) across 10 European centers and has been designed to assess the safety and effectiveness of Kalios™ device for the surgical treatment of mitral regurgitation with optional intra-operative and/or post-operative non-surgical adjustments.

The primary performance endpoint success rate of the mini-invasive annuloplasty surgery was defined by an absence of mitral regurgitation of grade¹ >2 at one year.

These 16 patients have been recruited in 3 centers (Vienna, Cotignola and Passau), 9 patients had primary (degenerative) mitral regurgitation and 7 patients had secondary (functional) mitral regurgitation. Mean age was 66 years and 75% of patients had a functional class NYHA² III or IV. Mitral regurgitation grade was ≥ to 3 in 14 patients.

In half of the cases the patients benefited from a concomitant cardiac surgery intervention on top of the Kalios™ surgical ring. In 4 cases (25%), a post implantation adjustment was performed due to remaining or relapse regurgitation of grade 3 to 4. Three adjustments were performed perioperatively and one adjustment at 11 months post implantation with no need for the patient to undergo another long lasting and significant open heart surgical procedure.

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

²NYHA: The NYHA classification is a scale of diagnostic, prognostic and therapeutic interest that expresses the clinical severity of heart failure.



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Mitral regurgitation grade was reduced at 30 days by at least 2 grades as compared to baseline and no patients had mitral regurgitation grade >2. These results were maintained at 6 months.

Functional status also improved as no patients had NYHA > II at discharge and these results were maintained up to 6 months.

Safety profile was excellent with no death reported, 3 major cardiac events in 2 patients were observed at 30 days. We report 3 explants related to learning curve.

Pr. Martin Andreas, Associate Professor at the Department of Cardiac Surgery, Medical University of Vienna stated: "*We have included in our institution 11 patients at the time of this interim analysis. We are very satisfied with the device, its ease of implantation and the potential to manage residual or recurrent mitral regurgitation at a later stage with no need for repeating open-heart surgery.*"

Pr. Alberto Albertini, Chief of Cardiovascular Surgery Division at Maria Cecilia Hospital GVM Care & Research in Cotignola added: "*The results of the implanted patients are excellent. In our center we successfully adjusted the percutaneous ring in a patient with recurrence of functional mitral insufficiency 11 months after surgery. This small transcatheter procedure avoided another cardiac intervention. This technique offers the opportunity to treat recurrent mitral insufficiency after repair over time for both functional and degenerative mitral pathologies.*"

Affluent Medical's Chief Medical Officer Prof. François Laborde added: "*The Kalios™ ring adjustment features represents a paradigm shift in the patient management and follow up. It will change the way patients are monitored, accelerate or anticipate treatment of mitral incompetence without repeating open-heart surgery. Kalios™ is a unique opportunity to improve patient conditions and way of life while also potentially providing medico-economic benefits for healthcare payors.*"

"This is a significant milestone for our Kalios™ clinical program and a future major alternative for physicians in treating patient as well as for payors. We wish to thank all Optimize II investigation centers for their successful implantations", stated Michel Finance Chairman and CEO of Affluent Medical."

Affluent Medical anticipates presenting a more exhaustive analysis and a larger data set at the leading European Association of Cardio Thoracic Surgery (EACTS) in Milan, October 2022.

About Kalios™

Kalios™ is the only ring designed for mitral valve repair optimised for minimally invasive cardiac surgery and allowing multiple post-operative readjustments via the transcatheter route - without invasive reoperation. It is therefore a unique hybrid technology. A pivotal study is currently underway in Austria, Germany, Switzerland and Italy and 23 patients have already been recruited.



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About Affluent Medical

Affluent Medical is a French player in MedTech, founded by Truffle Capital, with the aim of becoming a global leader in the treatment of heart and vascular diseases, which are the leading cause of death worldwide, and of urinary incontinence, which today affects one in four adults. Affluent Medical develops innovative, next-generation minimally invasive implants to restore essential physiological functions in these areas. The four major technologies developed by the Company are currently in the pre-clinical and clinical study phase. Karios™ is set to be the first medical device to be marketed in Europe.

For more information, please visit: www.affluentmedical.com

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