



**AFFLUENT MEDICAL ANNOUNCES THE SUCCESSFUL CONCLUSION  
OF ITS *OPTIMIZE* CLINICAL STUDY FOR KALIOS,  
THE BREAKTHROUGH MITRAL VALVE REPAIR DEVICE.**

- **Positive results of the *OPTIMIZE* feasibility clinical study on 5 patients implanted between January and May 2018.**
- **Primary endpoint has been attained proving surgical safety of KALIOS.**
- **KALIOS is the first fully adjustable mitral valve repair device, designed for the percutaneous treatment of both residual and recurrent Mitral Regurgitation (MR).**
- **Affluent Medical plans on launching the device in Europe at the end of 2020, subject to the obtention of marketing authorization.**

**Paris, France, September 4<sup>th</sup>, 2018** – Affluent Medical, a new French *medtech* player specialized in innovative, minimally invasive implants designed to restore key physiological functions in patients suffering from major cardiac, vascular and urinary diseases, announces today the positive conclusion of its *OPTIMIZE* first clinical study for KALIOS, its adjustable mitral repair device. KALIOS has been implanted in five patients between January and May of the current year by Prof. Martin Andreas, Principal Investigator of this feasibility study, at the Vienna General Hospital (AKH). The first results of the study show that the primary endpoint has been attained, proving the surgical safety of KALIOS.



KALIOS can treat post-operative the residual valve insufficiency, that can affect patient immediately after valve surgery, as well as the recurrent one, that can occur at a later stage after surgery. The size and shape of the implanted device can be adjusted percutaneously multiple times in the months/years following the surgery, offering patients a personalized treatment.

“Patients suffering from functional mitral regurgitation have today no mitral repair option that can address the recurrence, that is the progression of the disease post-surgery. Besides, the percentage of patients that receive suboptimal surgical treatment, that is who leave the operating room with a residual mitral regurgitation or simply and insufficient valve coaptation, remains considerable. Both factors make the long-term outcomes of repair surgery unsatisfactory, which represents a need still unmet by the current structural heart therapies. Our KALIOS repair technology has the potential to satisfy this need and, with today results, we have proven that this can be done simply and safely”, **comments Daniele Zanotti Affluent Medical’s CEO.**



The commercial launch of KALIOS in Europe is planned by the end of 2020, subject to the obtention of the authorization from the regulatory authorities. It targets the global market of mitral valve repair and replacement devices, expected to reach \$3.5 billion by 2022 and growing at a rate of 35% per year between 2017-2022, driven by the technological innovation of devices with percutaneous features<sup>1</sup>.

The *OPTIMIZE* study for KALIOS is part of Affluent Medical's clinical development plan, aiming at obtaining CE marking for each of the four products – KALIOS, ARTUS, KARDIOZIS and EPYGON - between the end of year 2020 and year 2022.

### About Affluent Medical

Affluent Medical is a new French *medtech* player with the ambition to become one of the European leaders in the treatment of heart and vascular diseases - which are the leading cause of death throughout the world - and of urinary incontinence today affecting one in four adults, subject to the achievement of complementary steps and obtention of regulatory authorization. Affluent Medical is developing innovative, next-generation *best-in-class* minimally invasive implants to restore key physiological functions in these areas. The company's four medical devices are currently in preclinical and clinical validation phases, and a first medical device is expected to be launched by 2020. Affluent Medical was incorporated in February 2018, from the combination of four technologies drawn from Truffle Capital's portfolio: KARDIOZIS, KALIOS, EPYGON and ARTUS.

For more information: [www.affluentmedical.com](http://www.affluentmedical.com)

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#### Press

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<sup>1</sup> Azoth Analytics – 2017: Transcatheter Mitral Valve Repair and Replacement (TMVR) Market – Opportunities and Forecast 2017-2022