



PRESS RELEASE

KEPHALIOS reports first patient implanted with Kalios, its breakthrough mitral valve repair device

Kalios, the first balloon-adjustable mitral ring, was successfully implanted in a living human at the Medical University of Vienna

Aix-en-Provence – January 18 2018 – KephaliOS reported today that Kalios, the company’s innovative, balloon-adjustable mitral ring aimed at correcting **mitral regurgitation (MR)**, was successfully implanted for the first time in a MR patient on January 1st, at the **Vienna General Hospital (AKH)**, in Austria. The patient is one of 5 scheduled to receive the device as part of “OPTIMISE,” a first-in-human trial designed to test the feasibility and surgical safety of Kalios (the first results are expected in Q2 2018).

Intended for patients suffering from MR, which has a global prevalence of about 1%, Kalios is based on a proprietary disruptive annuloplasty technology, aimed at personalizing MR’s surgical treatment. Drawing on the proven implant technique of “Carpentier” rings, Kalios’ size and shape can be adjusted multiple times within months following the surgery, through minimally invasive interventions, as a way to optimise the mitral valve repair, while protecting the ventricular function.

According to Associate Prof. Martin Andreas, who performed the surgery as Principal Investigator of OPTIMISE: *“KephaliOS’ technology is ideal to treat either residual MR directly after mitral repair surgery or recurrent MR, which affects mostly patients suffering from functional MR. This population has been particularly difficult to treat so far, due to the progression of the disease post-surgery.”* Prof. Guenther Laufer, Head of the Department of Cardiac Surgery at AKH, said: *“With KephaliOS’ repair technology, this poor outcome could be prevented, thanks to an “optimised” surgical strategy allowing long-term adjustments of the implant. KephaliOS’ device could become an important tool to avoid redo surgery. However, the results of the ongoing clinical trials have to be carefully analysed.”*

“KephaliOS—along with its main shareholder—Truffle Capital, is pursuing a vision of ‘smart implantable devices’. By offering an innovative design, adaptable to individual patients’ needs, these devices, which are based on proprietary technical solutions, can help meet major therapeutic needs, while minimising the risks and obstacles for patients. In that regard, our mitral annuloplasty system is well-positioned, within the field of structural heart disease, to satisfy the need for a more effective mitral repair. This surgical implant will not only help surgeons overcome the current treatment limitations, but also improve the long-term management of patients, which is a major concern for cardiologists. Our goal is to achieve an adequate leaflet coaptation after the surgery and to retain it over time, by adjusting the device via an easy and quick percutaneous procedure. In our view, this innovation may pave the way to expand the surgical treatment of functional MR to patients who are currently denied surgery, due to the risk of poor long-term outcomes,” said Daniele Zanotti, CEO of KephaliOS.



About Mitral Regurgitation

Mitral regurgitation (MR) or mitral insufficiency or mitral incompetence is a disorder of the heart in which the mitral valve does not close properly when the heart pumps blood. It manifests itself by an abnormal, backward leakage of blood from the left ventricle to the left atrium through the mitral valve, when the left ventricle contracts, due to a prolapse or poor coaptation (contact) of the leaflet. MR affects about 1% of the population and 8% of the people of 65. MR patients suffer from a serious deterioration of their QOL and have a poor prognosis, including heart failure and early death.

About KephaliOS

Co-founded by Truffle Capital and by inventors Piergiorgio Tozzi and Daniel Hayoz in 2011, KephaliOS is based in Aix-en-Provence, France. It has developed the disruptive technology of balloon-adjustable annuloplasty ring for the treatment of mitral regurgitation and is engaged in the research of innovative minimally invasive heart implants. As the leader of the MIVANA consortium, KephaliOS federates two companies, Epygon and MDB Texinov, as well as the IFTH research center (Institut Français du Textile et de l'Habillement), with the aim to create a new cardiovascular sector in France. MIVANA raised € 20 million in private contributions and received € 8.6 million in funding from BPI France.

About Truffle Capital

Founded in 2001 and based in Paris, Truffle Capital is an independent venture capital company focused on setting up and financing, from inception to commercial stage, start-up companies with disruptive technologies and the potential to become market leaders in life sciences and IT. Chaired by Patrick Kron alongside Truffle founders and CEOs Philippe Pouletty, MD and Bernard-Louis Roques, Truffle Capital manages assets of \$1.1 billion (€920 million). Since its inception, Truffle has been very active and successful with medical implants start-up such as Vexim, Carmat, Symetis, or Epygon and has funded over 80 companies, mostly in life sciences and IT.

About Medical University Vienna

The Medical University of Vienna (short: MedUni Vienna) is one of the most reputed and important medical education and research facilities in Europe. With 8,000 students, it is currently the largest medical training center in German-speaking countries. With 27 university hospitals, 3 clinical institutes and 12 medical theory centers, along with numerous highly specialized laboratories, it is one of Europe's leading research establishments in the biomedical sector. More than 48,000 m² of research area are available for clinical research.

About AKH Wien – Vienna General Hospital

The Allgemeines Krankenhaus der Stadt Wien (General Hospital of the City of Vienna) – Medical University Campus – treats around 100,000 inpatients annually and an additional 1.1 million outpatients. Next to the medical staff of MedUni Wien, AKH Wien offers a nursing staff of around 3,000 people and over 1,000 medical-associate, therapeutic and health-diagnostic professionals.

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