



**AFFLUENT MEDICAL ANNOUNCES THE  
LAUNCH OF THE MINERVA FIRST-IN-HUMAN CLINICAL STUDY OF EPYGON,**

- **EPYGON is the first native-like transcatheter mitral valve replacement technology aiming at achieving better clinical outcomes**
- **The Austrian Competent Authority has granted authorization to start patient enrollment at Vienna General Hospital (AKH)**
- **The EPYGON valve has the potential to become a new paradigm in the treatment of functional mitral regurgitation patients as it could also improve left ventricle function**
- **Following approval of the clinical study in Austria, Epygon received € 2.3 million in grants in early May from the French public investment bank Bpifrance as part of the PSPC MIVANA project**
- **New financing obtained for a total amount of €15.8 million<sup>1</sup>**

**Aix-en-Provence, June 24, 2020** – Affluent Medical is a French MedTech company specialized in innovative, minimally-invasive implants designed to restore key physiological functions in patients suffering from structural heart diseases, as well as urinary incontinence. The company announces today the start of the MINERVA First-In-Human clinical study of EPYGON, the first “physiological” transcatheter mitral valve prosthesis.

**Professor Martin Andreas**, Principal Investigator of this First-In-Human study at the Vienna Medical University, stated:

*“The left ventricle vortex is a physiological process which is abolished after standard surgical mitral valve replacement. It is well known that survival is decreased after mitral valve replacement compared to mitral valve repair, which protects the vortex. Therefore, this feature of the Epygon valve has the potential to improve patient outcomes. We hope to observe this unique advantage of the Epygon transcatheter valve in our patients with respect to all other valve replacement technologies, whether via transcatheter or open surgery”*

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<sup>1</sup> See press release dated June 24, 2020 “Affluent Medical announces €15.8 million in new financing and strengthening of its board of directors.”



**Michel Finance**, CEO of AFFLUENT MEDICAL, said:

*“The start of the MINERVA pilot trial is a major step forward for Affluent Medical. Epygon is a world premiere and a potential best-in-class valve in a market where physiology has been overlooked for decades. This pilot study aims to confirm the improved clinical outcomes already demonstrated in preclinical testing. It should open up a new era both for surgeons and patients, with physiology as a key factor in cardiac surgery. Epygon is unique, notably as it mimics the physiological human valve.”*

**The MINERVA study: First-In-Man Clinical Study for the Treatment of Severe Mitral Valve INSufficiency with the Epygon™ TRanscatheter Mitral VAlve System.**

MINERVA is a pilot, prospective, non-randomized, single-arm, multicentric and international study. It is designed to enroll up to 20 patients in 3 centers of 3 different European countries (Austria, Italy and Spain). Patient enrollment is planned to be completed by Q1 2021 and the primary endpoints results will be evaluated after one year of follow-up .

**EPYGON, a breakthrough mitral technology designed to treat both left ventricle disease and mitral regurgitation at the same time**

Today, 4 million patients across the United States, Europe and Asia suffer from severe mitral valve regurgitation with no access to optimal therapies.



Epygon is the first transcatheter mitral valve designed to restore the physiological blood flow vortex and treat left ventricle disease, in particular in so-called “functional” patients.

No mitral valve prosthesis currently on the market or in development was designed to restore the vortex.

The unique concept and design of the Epygon valve is expected to achieve high procedural success, restore left ventricle physiological flow, and offer excellent performance in terms of the absence of thrombus formation and LVOT obstruction, while eventually also alleviating left ventricular effort.

The safety and efficacy of EPGON were tested in preclinical models and the CE marking pivotal trial is slated to begin at the beginning of 2022, for planned introduction on a global market currently growing at a rate of 35% per year and expected to reach \$3.5 to 5.0 billion by the end of 2022.



### **About Affluent Medical**

Affluent Medical is a French *MedTech* company founded by Truffle Capital with the ambition to become a European leader in the treatment of heart and vascular diseases, which are the world's leading cause of death, and of urinary incontinence, which today affects one in four adults. Affluent Medical develops innovative, next-generation minimally-invasive implants to restore key physiological functions in these areas. The company's four major technologies are currently in preclinical and clinical phases, and a first medical device is expected to be launched by 2022.

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

### **About the PSPC MIVANA project :**

The PSPC MIVANA project was built to create a cluster for innovative implantable medical devices targeting the mitral valve. This innovative collaborative project is led by Affluent Medical (Epygon and Kephalius), a pioneering start-up and leader in the growing market segment of implantable cardiac devices. The project also includes two other partners: –MDB Texinov, a SME specialized in technical textiles that is involved in the design and automation of assembly processes and the industrialization of new products. –The French Textile and Clothing Institute (IFTH) involved in the selection of textile materials / structures and the design of prototypes.

The project aims to develop two proprietary cardiovascular Implantable Medical Devices (IMDs) to treat mitral valve diseases at different stages through repair or replacement. This R&D project, accompanied and labeled by the Eurobiomed (Marseille, Montpellier pôle porter), Techtera (Lyon) and Medicen (Paris) competitiveness clusters, has won the PSPC (Structuring Projects for Competitiveness) call for projects of Bpifrance Financement. The MIVANA consortium is investing nearly € 30 million, and is funded for up to € 8.6 million.

### **Media contacts**

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