

PRESS RELEASE

Aix-en-Provence, 27 May 2021- 8.00 a.m.



Affluent Medical published preclinical data in the renowned **ANNALS OF THORACIC SURGERY** confirming the potential of its Epygon mitral valve to restore blood flow and reduce the risk of cardiac insufficiency.

- Preclinical *in vivo* results published in *The Annals of Thoracic Surgery* confirm the Epygon mitral valve ability to adapt to the heart while restoring the native-like blood flow.
- Epygon has been designed to replicate the human physiology to allow a better recovery of the left ventricular function minimizing the risk of cardiac insufficiency.
- A first-in-human clinical trial in 15 patients will be initiated in the 2nd semester 2021 and a pivotal study will be initiated in the US and Europe in the 2nd semester 2022.

Affluent Medical is a French MedTech company specialized in innovative, minimally invasive implants designed to restore key physiological patterns in patients suffering from structural heart diseases, as well as urinary incontinence. The company today announced the publication of preclinical data of its mitral valve Epygon in the renowned ***Annals of Thoracic Surgery*** on “*Novel transcatheter mitral prosthesis designed to preserve physiological ventricular flow dynamics*” ([https://www.annalsthoracicsurgery.org/article/S0003-4975\(21\)00646-9/fulltext](https://www.annalsthoracicsurgery.org/article/S0003-4975(21)00646-9/fulltext)).

The results demonstrate that the Affluent’s mitral valve Epygon is easy to implant, deploys swiftly and reproduces the natural physiological filling of the left ventricle allowing the reestablishment of the native-like blood flow (“Vortex”). The valve has proven to be safe, and no major complication occurred following the implantation.

Prof. Marcio Scorsin, first author said: « *We feel honored by this publication in such a prestigious peer reviewed journal like The Annals of Thoracic Surgery. I would like to thank all authors for their contributions to the first of its kind article. These preclinical in vivo results confirm the expected hemodynamic performance of the Epygon transcatheter mitral valve. Further clinical studies should now confirm the ability of the Epygon valve to foster left ventricular recovery to address this under-diagnosed mitral valve regurgitation disease and unmet patient needs.* »

Epygon shows several advantages compared to currently available or in development mitral valves. thanks to its D-shape, its asymmetric design and its single leaflet, the large opening



PRESS RELEASE

Must not be published, transmitted or distributed directly or indirectly in the United States of America, Canada, Japan or Australia.

Promotional communication

of the valve efficiently imitates the native natural asymmetry and restores the physiological blood flow. Importantly, in contrast to other mitral valves, Epygon does not deteriorate the left ventricle over time. In addition, it is easy to implant and takes less than 10 minutes to deploy. The delivery system is advanced to ensure optimal central placing inside the native mitral valve.

Michel Finance, Chairman and CEO of Affluent Medical, said: *“The publication of the preclinical data in a peer review journal is an important achievement for Affluent Medical. It brings us one step closer to establishing Epygon as the best-in-class mitral valve which has the potential to become a game changer for patients suffering from cardiac insufficiency. Epygon is the first valve that imitates the human physiology and is therefore able to restore the natural blood flow in the body to reduce the risk cardiac insufficiency. A first-in-human clinical study in 15 patients will start soon. A pivotal trial will be initiated in the 2nd semester 2022. Cardiovascular diseases are the number one cause of death globally, taking an estimated 17.9 million lives each year. With the development of Epygon as well as Kalios, our adjustable mitral valve ring, Affluent Medical aims at addressing the huge unmet medical need in the cardiovascular field offering novel, minimally invasive and effective medical solutions.”*

About Epygon

Epygon is the first transcatheter mitral valve designed to restore the physiological blood flow vortex and treat left ventricular disease, 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 ventricular physiological flow, and offer excellent performance in terms of the absence of thrombus formation and LVOT obstruction, while also alleviating left ventricular effort. The safety and efficacy of Epygon were tested in preclinical. The pivotal study will be initiated in the second half of 2022 in Europe and the United States with an objective to obtaining CE marking in the second half of 2025 and registration with the FDA at the end of 2025 subject to the impact of the Covid-19 of going through the various clinical stages and obtaining the necessary funding.

About Affluent

Affluent Medical is a French MedTech company founded by Truffle Capital with the ambition to become a world 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. A first medical device is expected to be launched by 2023 with Kalios in Europe.

For more information: www.affluentmedical.com



PRESS RELEASE

Must not be published, transmitted or distributed directly or indirectly in the United States of America, Canada, Japan or Australia.

Promotional communication

Media relations

AFFLUENT MEDICAL

Jérôme Geoffroy, CFO

investor@affluentmedical.com

Tel.: +33 (0)4 42 95 12 20

DGM CONSEIL

thomasdeclimens@dgm-conseil.fr

quentin.hua@dgm-conseil.fr

Tel.: +33 (0)1 40 70 11 89