PRESS RELEASE

# Pre-submission dossier for the 510(k) of medical device Kalios™ filed with FDA for review

- **Assessments of the FDA review to be discussed in a meeting towards the end of the first quarter.**
- **Process meant to support Affluent Medical to optimize market authorization for Kalios™ in the U.S.**
- **Kalios™ is the first mitral annuloplasty device for patients with mitral valve regurgitation that can be percutaneously adjusted to optimize valve repair on a beating heart, thereby avoiding repeat of invasive open-heart surgery.**

**Aix-en-Provence, 15 January 2024 - 5:45 pm - Affluent Medical (ISIN: FR0013333077 – Ticker: AFME), a French clinical-phase MedTech company specialising in the international development and industrialisation of innovative medical prostheses,** today announces that it has submitted the pre-dossier for the 510(k) of its medical device Kalios™ to the U.S. Food and Drug Administration (FDA).

On December 20th, 2023, Affluent Medical received the FDA acknowledgment letter for the filing of the pre-submission process to evaluate the 510(k) pathway for future market assessment of the Kalios™ device in the United States. A 510(k) is a premarket submission made to the FDA to demonstrate that the device under evaluation is as safe and effective, that is, substantially equivalent, as the legally marketed device.

End of Q1 2024, Affluent Medical will schedule a meeting with the FDA to discuss their substantive feedback on the pre-submission dossier. The assessments of this meeting will be considered for the market authorisation pathway for Kalios™ in line with U.S. regulations.

The pre-submission process is a strategic step that carefully considers the FDA's feedback in order to improve the quality of subsequent submissions, shorten total review times, and facilitate the development process for new devices. Interactions provided within pre-submissions are likely to contribute to a more efficient and transparent review process for the FDA and the submitter.

"*Early interaction with the FDA and receiving the agency's feedback gives us valuable guidance for our application preparation in the U.S.*," explains **Sébastien Ladet, Chief Executive Officer of Affluent Medical.** "*The process is meant to support Affluent Medical in the optimization of the market authorization process for Kalios™ by focusing on the important information needed for FDA approval.*"

## Positive interim results for Kalios™' pivotal Optimize II study at one year represent early validation of efficacy and safety profile

Affluent Medical presented in September 2023 an intermediate dataset of the Optimize II pivotal study on 20 patients treated in five centers in Europe after one year implementation. At one year, none of the patients had MR >2+, thus meeting the pre-defined efficacy endpoint of the study. The safety profile of the study was excellent: no death, no myocardial infarction, no valve thrombosis and no endocarditis were reported, up to one year.

In line with the analysis of positive data after one year from the European Optimize II study, the Company has decided to focus resources on the U.S. market, which is the world's largest unified medtech market. Additionally, obtaining approval in the U.S. is well aligned with the Company's strategy to secure commercial partners, which are mostly located in the U.S.

Kalios™ is the first mitral annuloplasty device that can be adjusted percutaneously to treat both residual and recurrent mitral valve insufficiency, at any time after implantation, repeatedly and with a beating heart, thereby avoiding repeat open-heart surgeries.

Mitral valve regurgitation is a serious and potentially fatal disease affecting 2% of the world's population, or approximately 160 million people. Affluent Medical believes that Kalios™ could avoid further interventions for

potentially 30-40% of patients over five-years. The market for mitral valve repair surgery is estimated to be worth $1.5 billion in the U.S.-Europe region in 2023, growing at 3.5% per year.

**About Affluent Medical**

Affluent Medical is a French MedTech company, founded by Truffle Capital, with the ambition to become a global leader in the treatment of structural heart diseases, which are the world's leading cause of mortality, and urinary incontinence, which currently affects one in four adults.

Affluent Medical develops next-generation, mini-invasive, innovative, adjustable, and biomimetic implants to restore critical physiological functions. The product candidates developed by the Company are currently in preclinical and clinical studies.

Kalios, the first mitral adjustable annuloplasty ring, should be the first Affluent Medical device to be marketed.

Subject to raising the necessary funds to finance its strategy and to positive results from ongoing clinical studies, the Company's ambition is to gradually commercialize its products from the end of 2025/early 2026.

For more information, visit www.affluentmedical.com

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