PRESS RELEASE

Affluent Medical announces 10th successful human implantation of its Artus urinary sphincter, marking completion of the pilot phase

- **Completion of the pilot phase of the European multicenter clinical study in humans with the successful 10th minimally invasive implantation of the Artus urinary sphincter.**
- **100% successful activation of implanted devices to date.**
- **Good clinical safety profile observed during pilot phase.**
- **Promising preliminary performance results collected on the first patients.**

Aix-en-Provence, January 30, 2025 – 5:45 p.m. CET – Affluent Medical (ISIN: FR0013333077 – Ticker: AFME – "Affluent"), a French clinical-stage medical technology company specializing in the international development and industrialization of innovative implantable medical devices, today announced the successful completion of the pilot phase of the clinical study of the Artus system, an artificial urinary sphincter (AUS) for the treatment of stress urinary incontinence in men.

The pilot study cohort consists of ten men, with the primary objectives being device activation at six weeks after surgery and safety profile assessment at eight weeks.

The tenth implantation of the Artus artificial urinary sphincter was successfully performed in the second week of January 2025 in Poland, marking the end of patient enrollment for the pilot phase. The first patient was implanted in Q2 2024 at Thomayer University Hospital in Prague, Czech Republic, by Dr. Zachoval.

The device was implanted in 10 patients, with each procedure lasting approximately 40 minutes due to the innovative design of the Artus sphincter. To date, 100% of devices have been successfully activated and the safety profile remains positive.

"This first phase of the clinical study demonstrates the safety of the Artus device and the ease of use for minimally invasive procedure in men. All conditions are in line to continue the next phase of the clinical study", **emphasizes Prof. Nicolas Barry Delongchamps, Prof. of Urology, Cochin Hospital, Paris, and member of the Scientific Board of Affluent Medical.**

The results from this initial clinical phase will guide the execution of the pivotal phase, scheduled to begin in Q2 2025. This phase aims to validate the device's performance in reducing incontinence in several dozen patients.

"*The completion of the pilot study for our Artus device marks an important milestone for Affluent Medical and patients suffering from urinary incontinence. The initial performance results are promising, enabling us to proceed to the pivotal phase to demonstrate these findings on a larger scale. As the safety profile is good, it is also an opportunity to start the clinical evaluation of the device in women, who represent about 80% of patients suffering from urinary incontinence*", **comments Sébastien Ladet**, **CEO of Affluent Medical**.

Submission of the clinical study file for women

Urinary incontinence significantly impacts the quality of life of patients, particularly women, who often experience psychological and isolation disorders, as demonstrated by a meta-analysis by Pizzol et al, with a study carried out on 25,000 women.

With one in three women and one in six men[1] suffering from urinary incontinence in their lifetime, Affluent Medical has developed an implantable device for both men and women.

The prevalence of urinary incontinence (UI) in women ranges from 16% to 62% varying with age, with stress urinary incontinence (SUI) being the most common subtype.

The Company will submit the dossier in order to begin a pilot study in women in the first half of 2025, aiming to extend indications for its Artus urinary sphincter.

Artus is an implantable artificial urinary sphincter designed to treat moderate to severe urinary incontinence in men and women. Controlling the opening and closing of the urethra, it is activated by a remote control and adapts to the patient's lifestyle.

Affluent Medical emphasizes that urinary incontinence, affecting more than 400 million people worldwide, is a major public health problem. Few innovations have been introduced in this market for 40 years, leaving a population of patients suffering from reduced quality of life and psychological distress associated with this condition.

According to Optima Insights, the global market for medical devices to treat urinary incontinence (including slings, neurostimulators and artificial sphincters) could reach $4.3 billion by 2027, with an annual growth rate of 11% between 2019 and 2027. The economic cost of this disease to healthcare systems is estimated at $7 billion per year in European countries and up to $66 billion in the United States[2].

About Affluent Medical

Affluent Medical is a French medical technologies company, founded by Truffle Capital, that aims to become a global leader in the treatment of structural heart diseases, one of the world's leading causes of mortality, and urinary incontinence, which currently affects one in four adults.

Affluent Medical develops next-generation implants that are minimally invasive, innovative, adjustable and biomimetic, designed to restore essential physiological functions. The candidate products developed by the Company are all undergoing clinical studies in humans.

Subject to raising the funds necessary to finance its strategy and the positive results of ongoing clinical studies, the Company aims to gradually market its products from 2026, directly or indirectly.

For more information, please visit www.affluentmedical.com

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[1] *Source: State of the art Artus - Thomas Jefferson university hosp. Dr. Shenot – 2023*
[2] *Source: State of the art Artus*