AFFLUENT MEDICAL ANNOUNCES SIGNIFICANT CLINICAL MILESTONES WITH TWO OF ITS INNOVATIVE DEVICES: ARTUS & KALIOS

ARTUS, the first electronically activated artificial sphincter to treat urinary incontinence successfully initiates clinical trial in Paris

- First implantation in a patient performed.
- The clinical trial, taking place at the Cochin Hospital (Paris), aims to demonstrate the device's safety and effectiveness.
- Affluent Medical plans on launching the device in Europe in 2021[1].

KALIOS, the breakthrough mitral valve repair device, completes enrollment of its feasibility study

- Implantation of the device in a fifth and last patient.
- The first fully adjustable mitral valve repair device, designed to effectively meet the needs of patients with mitral insufficiency.
- Affluent Medical plans on launching the device in Europe at the end of 2020[1].

Paris, France, June 1st 2018 – Affluent Medical, a new French *medtech* player specializing in innovative, minimally invasive implants designed to restore key physiological functions for patients suffering from heart and vascular diseases, as well as urinary incontinence, today announces significant clinical milestones for two of its innovative devices: **ARTUS & KALIOS.**

"We are excited about these key milestones since these studies are part of Affluent Medical's clinical development plan, aiming at obtaining CE marking for each of our four products - KARDIOZIS, KALIOS, EPYGON and ARTUS, between the end of year 2020 / year 2022", said Daniele Zanotti Affluent Medical's CEO.

Successful start of the clinical trial with its ARTUS urinary implant

Affluent Medical has received authorization from the French regulatory agency on medical devices[2] to carry out its first clinical trial in France. This clinical trial aims at demonstrating the safety and effectiveness of its urinary implant, ARTUS. This device intends on helping men and women suffering from severe urinary incontinence to recover full control of their bladders.

[1] Subject to the obtention of necessary marketing authorizations.
[2] ANSM: Agence Nationale de Sécurité du Médicament et des produits de santé

A similar clinical trial is already under way in the Czech Republic. ARTUS has been implanted in a first patient at the end of May 2018, at the Cochin Hospital. In this clinical trial, ARTUS will be temporarily implanted in a total of three women.

The clinical trial, entitled "Feasibility of the implantation of the ARTUS Artificial Urinary Sphincter in women," in conducted at the Cochin Hospital in Paris. The ARTUS artificial urinary sphincter will be temporarily inserted in three women who have undergone a full urogenital tract ablation because of bladder cancer. The goal of the study is to verify, in the first place, that it is still possible to insert a catheter inside the bladder once the implant is in place. The study also aims at demonstrating the easy implementation and effectiveness of the device (adaptation to the neck of the bladder and activation of the implant).

ARTUS is an artificial urinary sphincter intended for both men and women. Fully concealable and easy to use via remote control, ARTUS will bring more comfort to patients by granting them easy control over their everyday urinary flow. Thanks to its optimized and adjustable pressure profile on the urethra, this device reduces the risk of decreased blood flow and tissue erosion of the urethra — two major complications experienced by patients with the artificial urinary sphincters currently available on the market.

A significant under-treated medical issue

Urinary incontinence affects one in four adults, with a female prevalence of 95%[3]. Yet, few implants are designed to help women recover control of their bladder. Men who have had their prostates removed or are treated for severe incontinence have more access to artificial sphincters; while women, who are the most affected by this pathology, are treated minimally or not at all due to a lack of products adapted to their anatomies. According to a study by IMS Consulting Group, in Western countries, only 3% of all artificial sphincter procedures involved women[3].

This is therefore a large market, combined with a truly unmet medical need to date. ARTUS aims at becoming the next standard of care in this market. The total global turnover of this market, in the field of urology, is today estimated at $ 7 billion per year in 2020, with a potential annual growth rate of 26% between 2017-2020[4].

ARTUS, a promising implant to be launched by 2021 in Europe

Video presentation: https://www.youtube.com/watch?v=-l1W1_sgMiM&feature=youtu.be

[3] Source: IMS Consulting Group Study - 2014: US Market Opportunity Assessment for ARTUS
[4] Source: Boston Scientific, Presentation Investor Day 2017, June 27 2017

Currently in clinical phase with ARTUS, Affluent Medical is planning a first market launch in Europe in 2021.Various studies in technical feasibility, safety, tolerance and efficiency have already been conducted both on animals and in laboratory. ARTUS has been clinically tested in Czech Republic, since February 28, 2018, at the Thomayer Hospital in Prague, under the same conditions as the upcoming study in France. A pivotal CE marking trial, which should involve 35 patients suffering from severe urinary incontinence, is planned for the end of 2018. Affluent Medical is also considering a trial in male patients by the end of 2019.

Completion of enrollment in a feasibility study for KALIOS

The implantation of the device in a fifth and last patient has been performed at the end of May 2018 by Prof. Martin Andreas, Principal Investigator of the study, at the Vienna General Hospital (AKH). The first results of the study, aiming at testing the feasibility and surgical safety of KALIOS, are expected in Q2 2018.

KALIOS can treat both residual postoperative leaks and chronic mitral insufficiency. The size and shape of the implant can be adjusted percutaneously multiple times in the months/years following the surgery, offering patients a personalized surgical treatment.

The European launch of the device is scheduled for the end of 2020, subject to the obtention of the necessary marketing authorizations. It targets a total global market expected to reach $3.5 billion by 2022 and growing at a rate of 35% per year between 2017-2022[(5)].

About Affluent Medical

Affluent Medical is a new French medtech player with the ambition to become one of the European leaders in the treatment of heart and vascular diseases - which are the leading cause of death throughout the world - and of urinary incontinence today affecting one in four adults, subject to the achievement of complementary steps and obtention of marketing authorization. Affluent Medical is developing innovative, next-generation minimally invasive implants to restore key physiological functions in these areas. The company's four medical devices are currently in preclinical and clinical validation phases, and a first medical device is expected to be launched by 2020.

Affluent Medical was born in February 2018, from the combination of four technologies drawn from Truffle Capital's portfolio: KARDIOZIS, KALIOS, EPYGON and ARTUS.

Affluent Medical announced it was planning an initial public offering on the Euronext Growth market in Paris and filed a *Document de Base* with the *Autorité des marchés financiers* (AMF) on May 28, 2018, with registration number I. 18-045.

For more information: www.affluentmedical.com

[5] Azoth Analytics – 2017: Transcatheter Mitral Valve Repair and Replacement (TMVR) Market – Opportunities and Forecast 2017-2022

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