



## **AFFLUENT MEDICAL MEETS A MAJOR MILESTONE WITH THE FIRST CLINICAL TRIAL OF ARTUS, ITS INNOVATIVE IMPLANT TO TREAT STRESS URINARY INCONTINENCE**

- **Positive results from the first clinical study on 3 patients implanted between May and September 2018**
- **The implant technique, via laparoscopy and open surgery, was validated, surgical safety was also verified**
- **Implantable in about 20 minutes with minimally invasive surgery, ARTUS is the first electronically activated artificial sphincter to treat stress urinary incontinence**
- **Affluent Medical is planning a market launch of ARTUS in Europe at the end of 2021, subject to regulatory approvals**

**Paris, France, November 5<sup>th</sup>, 2018** – Affluent Medical, a new French *medtech* player specialized 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 the successful completion of its first clinical trial in women for ARTUS, its new artificial urinary sphincter for the treatment of stress urinary incontinence.

This first step was aimed at validating the implantation technique via laparoscopy or open surgery, and to verify perioperative safety. This clinical study was jointly conducted in France, at the Cochin Hospital (Paris), and in the Czech Republic, at the Thomayer University Hospital (Prague), under the direction of Professors Barry Delongchamps and Zachoval, respectively. ARTUS was temporarily implanted in three women undergoing urogenital tract ablation via laparoscopy or open surgery. The functional performance of the implant on opening and closing of the urethra was also tested and confirmed.

In keeping with its goal of completing this first study in women before the end of 2018, Affluent Medical is set to launch a second phase of clinical trials in 2019, aimed at obtaining CE mark in 2021.

A debilitating and taboo condition, stress urinary incontinence affects several millions people worldwide, but there are currently very few effective treatments available.



**Professor Nicolas Barry Delongchamps**, urological surgeon at Cochin Hospital and the trial's coordinating investigator, is pleased with the positive results and looks forward to participating in future trials, which will involve permanently implanting the device in patients with stress urinary incontinence:

*“The ARTUS implant is a true technological innovation compared to the current therapeutic alternatives. Easily implanted with a laparotomy or laparoscopy, ARTUS limits postoperative complications and improves patients’ quality of life. The next clinical trials will help verify these upsides and we are very much looking forward to participating in this future evaluation.”*

**Daniele Zanotti**, CEO of AFFLUENT MEDICAL said:

*“The resounding success of this first clinical study in women highlights the huge therapeutic potential of ARTUS. Implantable in about 20 minutes by minimally invasive surgery, ARTUS will soon be a quick, reliable solution for millions of men and women around the world, who are currently presented with very few therapeutic options. I thank Professors Barry Delongchamps and Zacheval for renewing their interest in the project, following the completion of this trial. The participation of leading world experts is a major asset for the development and future adoption of our technologies.”*

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



ARTUS is an artificial urinary sphincter designed to mimic human physiology. Intended to assist the defective sphincter muscle, ARTUS is a unique device consisting of a flexible and biocompatible cuff placed around the urethra to compensate the weakness of the muscle in closing the urinary canal, thus avoiding urinary leakage. The opening and closing of the sphincter can be

controlled directly by the patient through a remote control that is connected via radio signals to the implanted device.

At any time, patients will be able to adjust the tightening of the urethra with the remote control, in order to tailor the device to their individual needs and avoid unnecessary strain on the urethral tissue.

### **A significant, under-treated medical issue**

Urinary incontinence affects one in four adults, with a female predominance of 95%<sup>1</sup>. Yet, few implants are designed to help women recover full 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 seldom or not at all due to a lack of products adapted to their anatomies.

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<sup>1</sup> Source: IMS Consulting Group Study - 2014: US Market Opportunity Assessment for ARTUS



According to a study by IMS Consulting Group<sup>1</sup>, in Western countries, only 3% of all artificial sphincter procedures involve women.

There 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 worldwide urology market, which is valued at \$7 billion per year in 2020, with a potential annual growth rate of 26% between 2017-2020<sup>2</sup>.

### About Affluent Medical

Affluent Medical is a new French *medtech* player 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 is developing 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 2020.

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

### Contacts

#### Affluent Medical

Henri Lefebvre, Chief Financial Officer  
[investor@affluentmedical.com](mailto:investor@affluentmedical.com)  
Tel.: +33 (0)1 82 28 46 00

#### Press

ALIZE RP  
Caroline Carmagnol / Wendy Rigal / Tatiana Vieira  
[affluentmedical@alizerp.com](mailto:affluentmedical@alizerp.com)  
Tel.: +33 (0)1 44 54 36 66

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<sup>1</sup> Source: IMS Consulting Group Study - 2014: US Market Opportunity Assessment for ARTUS

<sup>2</sup> Source: Boston Scientific, Presentation Investor Day 2017, June 27, 2017