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UroMems Granted Safer Technologies Program Designation from FDA for Smart Implant to Treat Stress Urinary Incontinence

STeP inclusion reflects the potential improvements in safety of its UroActive™ System

Grenoble, France & Minneapolis, Minnesota (April 20, 2023) – UroMems, a global company developing innovative, mechatronics technology to treat stress urinary incontinence (SUI), announced today that they have received Safer Technologies Program (STeP) designation from the U.S. Food and Drug Administration (FDA) for UroActive Smart Continence Therapy. STeP is a collaborative program intended to help reduce the time it takes to develop and obtain marketing authorization for eligible devices.

"We are delighted to receive this designation and excited to advance the development of our UroActive system – the first-of-its-kind fully automated AUS implant designed to treat SUI in both men and women," said Hamid Lamraoui, UroMems chief executive officer and co-founder. "We thank the FDA for acknowledging the importance of safety above all for patients."

UroActive is the first smart active implant that treats SUI, powered by a MyoElectroMechanical System (MEMS). This innovative system is placed around the urethral duct and is automatically controlled based on the patient's activity, without the need for manual adjustments, intending to provide patients with ease of use and a better quality of life than current options.

SUI, or involuntary urinary leakage, affects an estimated 40 million Americans and 90 million Europeans, and occurs when the pressure in the bladder exceeds that of the muscle (the sphincter) around the urethra, caused by activities involving high intra-abdominal pressure, like coughing, laughing and exercising. SUI significantly impacts quality of life, as it can be debilitating, and often leads to depression, low self-esteem and social stigma. While mild SUI is addressed by pelvic floor re-education and bulking agents, moderate and severe SUI historically have only had two options: mesh sling or artificial urinary sphincter.

"The STeP approval is proof that the FDA recognizes the potential for UroActive to improve upon safety for patients with severe SUI, while also designed for an improved surgical experience for the OR team, surgeons and most importantly, their patients," said Professor Pierre Mozer, UroMems chief medical officer and co-founder.

UroMems aims to restore the quality of life, dignity and self-esteem of millions of men and women worldwide suffering from poorly treated chronic conditions by the commitment to change the perception that these disorders are inevitable as one grows older and is simply something to endure with no real solution. UroMems is revolutionizing the treatment of SUI with smart active implants, using the

latest technological advances in the field of embedded systems and micro-technologies for the development of its groundbreaking solutions.

About STeP

Launched in January of 2021, the FDA's Safer Technologies Program is a voluntary program for certain medical devices and device-led combination products that have the potential to be safer than currently available treatments or medical diagnostics. The program is intended to help patients have more timely access to products by expediting their development, assessment, and review, while maintaining the FDA's standards for safety and effectiveness, data requirements, and quality of review.[1]

STeP participation does not imply product authorization. UroActive has not received marketing authorization from the FDA and is not available for sale in the United States.

About UroActive

UroActive is an active implantable electronic artificial urinary sphincter that is being developed to compensate for sphincter insufficiency in patients, both men and women, with SUI. It is based on a unique bionic platform using embedded smart, digital and robotic systems which, based on data collected from a patient, create a treatment algorithm that is specific for each patient's needs. The UroMems technology platform is protected by more than 100 patents and is designed to overcome the limitations of current solutions by optimizing safety and performance, patient experience and surgeon convenience.

About UroMems

Founded in 2011 by Professor Pierre Mozer, Hamid Lamraoui and Stéphane Lavallée, UroMems aims to restore the quality of life, dignity and self-esteem of millions of men and women worldwide suffering from untreated chronic conditions by the commitment to change the perception that these disorders are inevitable as one grows older and is simply something to endure with no real solution. The first challenge for the company will be applying embedded mechatronics methods and smart systems for treating urinary incontinence. Designed by urologists and collaborating scientists and engineers, UroActive intends to provide a new standard of care combining safety, efficacy, durability and ergonomics fitting any individual's lifestyle and anatomy.

Since the inception of the company, significant investments have been made for the development of UroMems' first product. This includes two financing rounds totaling 46 million euros, led by Wellington Partners, Bpifrance, Supernova Invest, b-to-v Partners AG, Cita Investissement, Hil-Invent, Financière Arbevel and the founders. The company has received several awards for innovation, including the Prix Galien Award Medstart'up and the Worldwide Innovation Challenge initiated by the French government. For more information, please visit www.uromems.com.

[1] https://www.fda.gov/news-events/press-announcements/fda-roundup-march-7-2023

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