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UroMems Completes First-in-Man Study Enrollment of Smart Implant for Stress Urinary Incontinence

Initial clinical trial results will inform pivotal clinical study in U.S. and Europe

GRENOBLE, France & MINNEAPOLIS, Minnesota (September 12, 2023) – [UroMems](#), a global company developing innovative, mechatronics technology to treat stress urinary incontinence (SUI), announced today that it has successfully completed enrollment in its first-in-man study of the UroActive™ System, the first smart automated artificial urinary sphincter (AUS) to treat SUI. The results of this initial clinical study will support design and implementation of UroMems' pivotal SUI trial in Europe and the U.S.

The study cohort is comprised of six men, all of whom underwent the UroActive implant procedure at either La Pitié-Salpêtrière University Hospital (AP-HP, Sorbonne University, Paris, France) or Nantes University Hospital (Nantes, France) with sequential enrollment as defined by the National Agency for the Safety of Medicines and Health Products (or ANSM, the French equivalent to the U.S. Food and Drug Administration).

“We are delighted with the rapid enrollment and positive early results we’re seeing in our [SOPHIA](#) study,” said Professor Pierre Mozer, UroMems chief medical officer and co-founder. “And with the treatment of our final study subject complete, we are now following the full clinical cohort in preparation for the pivotal study on our unique UroActive System.”

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. UroMems recently successfully completed the first-ever implant of the [UroActive system in a female patient](#), a milestone indicating a new era for millions of women suffering from SUI. UroMems also received the [Safer Technologies Program \(STeP\) designation](#) from the U.S. Food and Drug Administration (FDA) for UroActive.

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.

“We are indebted to these men for their participation in the SOPHIA study, and their enthusiastic response to their personalized therapy is heartening,” said Hamid Lamraoui, UroMems chief executive officer and co-founder. “This clinical investigation began less than a year ago and soon we will have six-month follow-up results for the complete cohort.”

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 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. 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 or in the EU.

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.