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UroMems Receives Clearance from the FDA and the French ANSM for Initiating Landmark Pivotal Clinical Study of UroActive® Smart Implant to Treat Male Stress Urinary Incontinence

IDE approval in both countries follows strong feasibility clinical results in France

GRENOBLE, France & MINNEAPOLIS, Minnesota (July 17, 2025) – UroMems, a global company developing innovative, mechatronics technology to treat stress urinary incontinence (SUI), received investigational device exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) and French National Agency for the Safety of Medicines and Health Products (ANSM) clearance, enabling the company to begin a first-of-its-kind pivotal clinical trial of the UroActive smart implant to treat stress urinary incontinence (SUI) in men.

This prospective, multicenter trial, called the SOPHIA2 study, will evaluate the safety and efficacy of the UroActive System, the first smart automated artificial urinary sphincter (AUS) for the treatment of SUI. The FDA IDE approval and ANSM clearance follow strong feasibility study results for both women and men in France.

“This marks a key milestone that has been more than a decade in the making, and brings us a significant step closer to delivering the relief from symptoms and return to life that UroActive has the potential to provide patients suffering from SUI,” says Hamid Lamraoui, UroMems chief executive officer and co-founder. “UroActive is the first and only smart automated AUS to reach this critical milestone, indicating a new era for millions of people suffering from SUI, while signaling an exciting transition for surgeons treating SUI across the U.S. and Europe.”

UroActive is powered by a MyoElectroMechanical System (MEMS). This innovative system is placed around the urethral duct and is controlled based on the patient’s activity, without the need for complex manipulation, intending to provide patients with ease of use and a better quality of life than current options.

Co-principal US investigators include Dr. Melissa Kaufman, FPMRS, professor and chief reconstructive surgery at Vanderbilt University in Nashville and Dr. Drew Peterson, FPMRS, professor at Duke University in Durham, NC. “We have seen first-hand the shortcomings of current SUI treatment options for our male and female patients,” said Dr. Kaufman on behalf of both co-principal investigators. “That’s why we’re so excited to be leading the SOPHIA2 trial, as it’s showing promise to provide significant improvements in addressing these issues. Based on the feasibility study data we’ve seen, UroActive has the potential to be a transformational technology.”

“We’ve seen exceptionally strong results for both men and women in France as part of the feasibility clinical study, including over one year with no need for revision nor explant and extremely high praise from patients who had been suffering from SUI for years,” said Professor Emmanuel Chartier-Kastler, Urology Chair, Sorbonne University and Pitié-Salpêtrière Hospital in Paris. “We look forward to conducting the pivotal SOPHIA2 study in France in lock step with the U.S. sites.”

SUI, or involuntary urinary leakage, affects an estimated 40 million Americans and 90 million Europeans. SUI significantly impacts quality of life, as it can be debilitating, and often leads to depression, low self-esteem and social stigma.

SOPHIA2 study will serve as the basis for UroMems’ regulatory submission to the FDA and supports its broader strategy to commercialize UroActive in the U.S. and European markets.

About UroActive
The UroMems technology platform is protected by more than 180 granted patents and is designed to overcome the limitations of current solutions by optimizing safety and performance, patient experience and surgeon convenience. UroActive is the first active implantable electronic artificial urinary sphincter (AUS) that is being developed to compensate for sphincter insufficiency in patients, both men and women, with SUI. It is based on a unique mechatronic platform using embedded smart, digital and robotic systems. UroActive has not received marketing authorization from the FDA and is not available for sale in the United States or in the EU. This project is financially supported by the European Innovation Council and France 2030.

For more information, please visit www.uromems.com.