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UroMems Reaches Significant Milestone: Successful Results in Clinical Feasibility Study of UroActive™ Smart Implant for Stress Urinary Incontinence Treatment

Successful primary and secondary results demonstrate proof of feasibility in male patients, paving way for launch of large-scale pivotal clinical study in the U.S. and Europe

GRENOBLE, France & MINNEAPOLIS, Minnesota (December 13, 2023) – UroMems, a global company developing innovative, mechatronics technology to treat stress urinary incontinence (SUI), announced today it has reached a significant milestone: the complete treatment cohort in the first-of-its-kind clinical feasibility study has successfully reached the six-month primary endpoints.

The feasibility assessment of the UroActive System was completed through a prospective multicenter clinical study. UroActive is the first smart automated artificial urinary sphincter (AUS) to treat SUI, and the only one to reach this critical milestone. The results of this initial clinical study support design and implementation of UroMems' pivotal SUI trial in Europe and the U.S. All six men are now implanted for at least seven months and up to fifteen months, with their devices operating as expected and no need for revision nor explant. In addition, extremely positive follow-up was received on secondary outcomes measures, including leak rate values and patient quality of life questionnaires.

UroMems received very positive feedback from all patients participating in the study cohort. "You have changed my life," stated one of the study participants. "I can do all activities again, without stress, without anxiety!"

"We're so pleased to see that our expectations about our device's performance were met or even exceeded and delighted to successfully treat and receive such high praise from patients who had been suffering from SUI for years," said Professor Pierre Mozer, UroMems chief medical officer and co-founder. "The results of this study will allow us to prepare our pivotal study which will be a major step in the development of UroActive."

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 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.

"The very compelling results of this first-in-man clinical study demonstrate the high potential of our technology and pave the way for larger clinical trials that will allow us to demonstrate all the benefits we are expecting to offer patients suffering from debilitating SUI," said Hamid Lamraoui, UroMems chief

executive officer and co-founder. “We could not have reached this important milestone without the enthusiastic participation of the men in this initial study cohort. We’re extremely grateful to them for being a vital part in bringing this potentially revolutionary treatment to market.”

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.

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 120 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.

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