MUVON THERAPEUTICS

PRESS RELEASE

MUVON Therapeutics Reports Positive Phase 2 Results for its First-in-Class Muscle Precursor Cell (MPC)-based Tissue-Engineered Therapy Showing Clinically Meaningful and Statistically Significant Benefits in Stress Urinary Incontinence

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Zurich, Switzerland, December 03, 2025 – MUVON Therapeutics AG, a clinical-stage biotechnology company, reports positive topline results from the Phase 2 clinical trial SUISSE-MPC2 (NCT05534269) evaluating its novel proprietary muscle precursor cell (MPC)-based tissue-engineered therapy platform in female stress urinary incontinence (SUI). The study met both its primary and secondary endpoints ($p<0.0001$), demonstrating significant, clinically relevant bladder health improvements, alongside a favorable safety profile and a treatment responder rate of 87% at 6 months. SUI represents a high unmet medical need, affecting more than 150 million women worldwide.

The single center, randomized, blinded Phase 2 study evaluated the efficacy and safety of MUVON's investigational tissue-engineered, autologous MPC-based therapy (MPCCOL) to treat SUI in women at two different dose levels. A total of 30 women with clinically diagnosed SUI and failed prior conservative treatments completed the study. The protocol consisted of obtaining a small calf-muscle biopsy under local anesthesia from which the patient's own (autologous) muscle precursor cells (MPCs) were isolated and expanded. These cells were used to prepare the final tissue-engineered product which was injected via the urethra into the external urethral sphincter muscle, using a proprietary, ultrasound-guided injection device, with the goal of regenerating the muscle and restoring function. Efficacy was assessed as change from baseline to 6 months after MPCCOL implantation in stress incontinence episode frequency (IEF) and 24-hour pad weight (reflecting urine loss).

The study met its primary endpoint, showing a clinically meaningful and statistically significant ($p<0.0001$) reduction in stress IEF at 6 months post-implantation (-60%) compared to baseline. While statistically significant reductions above 50% were observed for both doses, patients treated with the higher dose showed a greater improvement (-71%). Improvements were evident as early as 1 month post-implantation and sustained throughout the study duration. The study also met its secondary endpoint, showing a clinically meaningful and statistically significant reduction in urinary leakage. Pad weight decreased by 66% overall ($p<0.0001$), with both dose groups achieving >50% improvement and the higher dose showing higher efficacy (-76%). 87% of patients were classified as treatment responders, defined as showing a reduction of at least 50% in either IEF or 24-hour pad weight at 6 months post implantation compared to baseline.

No serious adverse events related to the tissue-engineered therapy were reported, as adjudicated by a data and safety monitoring board drawn from international experts in the field. No MPCCOL-related adverse events were reported and no device-related adverse effects occurred. MRI and clinical assessments confirmed tissue integrity in all patients. Overall, the MPC-based therapy was effective, safe and well tolerated.

"A change in incontinence episode frequency or reduction of urine leakage by at least 50% are recognized as clinically relevant. MUVON's novel therapy significantly exceeded this threshold and, along with the reported safety profile, is a potential game changer in the treatment of stress urinary incontinence," said **Prof. Philip Van Kerrebroek, MD, Prof. em. of Urology, University of Maastricht**, a study-independent urology expert.

"A big thank you to all the patients who were open to this innovative therapy, the researchers who carefully conducted the study and compiled all the data, and the MUVON team for their inspiration and tremendous support!" said **Prof. Cornelia Betschart, MD, Deputy Director Gynecology Clinic and Co-Director Pelvic Floor and Continence Center, University Hospital Zurich.**

"The consistency of improvement across all endpoints, alongside a favorable tolerability profile, further validates our therapeutic approach which directly addresses the functional muscle deficiency in SUI and could reduce reliance on synthetic material implants," said **Dr. Deana Mohr, Chief Executive Officer, MUVON Therapeutics**. "I'm thrilled for our team and thankful to the patients, their families and the study group for their dedication, time and courage."

MUVON and the study team plan to submit the full data set for publication in a peer-reviewed journal and to present the results at leading upcoming international medical conferences. The study was funded and supported by the University of Zurich and the Wyss Zurich Translational Center.

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About Stress Urinary Incontinence

Stress urinary incontinence (SUI) is defined as the involuntary loss of urine on effort, physical exertion or increased abdominal pressure. It is a highly prevalent disorder — affecting over 150 million women worldwide—with up to 40% of women over the age of 40 and one in four women after childbirth experiencing it. SUI severely impacts physical and psychological health, undermines the quality of life of those affected and imposes a high financial burden on employers, healthcare systems and society. Many patients with SUI do not achieve satisfactory relief with conservative measures such as Kegel exercises, which often show low and short-term efficacy. More potent surgical approaches, including bulking agent injections, surgical mesh, slings, and other devices, may exhibit drawbacks, from limited durability to risks associated with invasiveness or adverse events linked to the implantation of synthetic material into the body.

About MUVON Therapeutics AG

MUVON Therapeutics is dedicated to the discovery and development of personalized regenerative treatments with the goal of establishing them as an affordable standard of care, with an initial focus on the treatment of stress urinary incontinence in women. Our mission is to help the millions of patients suffering from serious debilitating diseases regain control of their lives by offering them minimally invasive treatment for regeneration of skeletal muscle tissue. Founded in 2020 as a clinical-stage life science spin-off from the University of Zurich, MUVON Therapeutics was accelerated by the Wyss Zurich Translational Center from 2021-2025. For more information about MUVON Therapeutics, please visit: www.muvon-therapeutics.ch