MUVON THERAPEUTICS

PRESS RELEASE

Muvon Therapeutics Announces Successful Phase I Clinical Study in Female Patients with Stress Urinary Incontinence using a Novel Regenerative Cell Therapy

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Zurich, Switzerland, September 8, 2022 -- Muvon Therapeutics AG, an innovative clinical-stage biotechnology company announced results from a Phase I clinical trial. This first study evaluating a proprietary cell therapy platform demonstrated the safety, feasibility and potential efficacy of autologous skeletal muscle injections into the bladder sphincter of women suffering from Stress Urinary Incontinence with the goal of naturally restoring strength and function over 6 months.

Stress Urinary Incontinence (SUI) is defined as the complaint of any involuntary loss of urine on effort or physical exertion. It is a highly prevalent and untreated disorder which affects over 200 million people worldwide. It has a severe impact on both physical and psychological health and imposes a high burden on quality of life on affected individuals. Up to 60 percent of women above the age of 40 are affected and twice as often as men following prostate surgery. All existing treatment options from conservative to interventional including Kegel exercises, bulking agents and surgical devices exhibit drawbacks ranging from limited, short-term relief to potentially serious adverse events.

Professor Daniel Eberli, MD PhD, the sponsor-investigator and Dr Florian Schmid, MD PhD, the co-investigator of this study from the Department of Urology at the University Hospital Zurich stated:

"We believe this cell therapy platform represents a truly unique mechanism to repair damaged sphincter muscle tissue using the body's own precursor cells without the need for any foreign body placement through surgery. We will be presenting our findings at the *International Continence Society Annual Meeting* (ICS) in Vienna, on Friday, September 9 at 11.45-11.52 in Hall D. Furthermore, we have submitted a manuscript reporting our complete findings to a leading scientific peer-reviewed journal."

ICS 2022 Abstract: #275 Transurethral Injection of Autologous Muscle Precursor Cells for the Treatment of Female Stress Urinary Incontinence – a Prospective and Randomized Phase I Clinical Trial

Dr Deana Mohr, CEO of Muvon Therapeutics added: "We have cleared the first major hurdle in our development program in the field of regenerative therapies where there is an extremely high unmet need and limited satisfaction with solutions. These results underscore rigorous pre-clinical testing and our ability to successfully extract muscle precursor cells from a patient, expand them in GMP laboratory conditions and inject into the sphincter muscle."

Dr John Coelho, Medical Affairs Leader noted: "The results of the Phase I feasibility study show that administration of this cell therapy is safe and well tolerated. We can now advance to the larger, adequately powered Phase II study with the intent of bringing a transformative option to patients with stress urinary incontinence."

Summary of Results:

Ten female patients were included in the study, of which 9 received treatment and completed all follow-up visits during the study period. Patients had a median age of 45 years and a median BMI of 24kg/m^2.

Importantly, the median functional urethral length (FUL) under stress was significantly longer with 30mm at 6 months follow-up compared to 25mm baseline (95% CI: 2.5 to 7, p = 0.009).

Median maximum bladder capacity was 610ml at baseline and 670ml at follow-up (95% CI: -45 to 140, p = 0.343).

Finally, quality of life (QoL) questionnaires showed an improvement ICIQ-scores from median 7 points at baseline to median 4 points at 6 months follow-up (95% CI: -7 to -2.5, p-value = 0.035).

Eight adverse events (AEs) were registered, of which 2 were potentially related to the treatment. One urinary tract infection (UTI) was diagnosed three weeks after injection and was successfully treated with a single dose of oral Fosfomycin. No serious AEs were registered.

The evaluation using magnetic resonance imaging of the pelvis revealed no evidence of aberrant tissue formation or necrosis and moreover showed increase in muscle volume in all patients.

For more information, please contact:

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About Muvon Therapeutics AG:

Muvon Therapeutics, a clinical-stage company, was founded as a spin-off from the University of Zurich. Muvon Therapeutics is dedicated to the discovery and development of personalized regenerative treatments as the primary standard of care. Our goal 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. For more information about Muvon Therapeutics, please visit: About Us | Muvon Therapeutics | Switzerland