Urovant Sciences® Receives "Best in Category" Award for Abstract Highlighting Investigational Novel Gene Therapy, URO-902, Presented at 2022 International Continence Society Conference

September 8, 2022, at 8:05 a.m. (PDT)

- *Interim 12-week analysis from the ongoing Phase 2a trial of an investigational novel gene therapy product, URO-902 (plasmid human cDNA encoding maxi-K channel),* ***receives International Continence Society (ICS) recognition for "Best in Category Prize: Overactive Bladder."***
- *Analysis from the trial suggests that* ***URO-902 may be an effective, safe, and well tolerated treatment option in women with overactive bladder (OAB) and urge urinary incontinence (UUI)****. Delivered at the Scientific Podium Session S1 - #6.*

IRVINE, Calif. and BASEL, Switzerland – September 8, 2022 – Urovant Sciences, a wholly owned subsidiary of Sumitovant Biopharma Ltd., receives coveted Best in Category award for an interim 12-week analysis from the ongoing Phase 2a trial of an investigational novel gene therapy product, URO-902 (plasmid human cDNA encoding maxi-K channel). The award-winning abstract was presented at the 2022 International Continence Society annual meeting on September 8, 2022. The 2022 ICS Annual meeting is being held September 7-10, 2022, in a hybrid format with both online and in-person participation (Vienna, Austria).

According to ICS, this honor is awarded to the highest-scoring abstract in each category. Scores are awarded by the ICS scientific committee members, external reviewers, and scientific session chairs. Abstracts are judged based on criteria of scientific merit, originality/topicality, and clinical relevance. Review the full 2022 Abstract Awards List here.

The podium presentation at ICS 2022 took place on Thursday, September 8, at 10:20 Central European Time (CET). Presentation #6 in *Scientific Podium Session S1*, Best Urology, was titled, "Efficacy and Safety of a Novel Gene Therapy (URO-902; pVAX/hSlo) in Female Patients with Overactive Bladder Syndrome and Urge Urinary Incontinence: Results from a Phase 2a Trial." The presentation described a prespecified, 12-week interim analysis of a 48-week multicenter, randomized, double-blind, placebo-controlled, dose-escalation study (NCT04211831). URO-902 was administered using direct intradetrusor injections via cystoscopy under local anesthesia. The presenting author was Kenneth Peters, M.D., Principal Investigator, and Chief of the Department of Urology at Beaumont Hospital, Royal Oak; Medical Director of the Beaumont Women's Urology and Pelvic Health Center; and Professor and Chair of Urology of the Oakland University William Beaumont School of Medicine in Rochester, Mich.

"We are delighted that this presentation has received the *Best in Category Prize: Overactive Bladder*, reflecting the high-quality scientific research involved," said Dr. Peters. "The promising interim safety and efficacy findings from this prespecified analysis indicate that URO-902 has potential as a therapeutic option for overactive bladder patients who have failed oral pharmacologic therapy."

At week 12, both URO-902 24 mg and 48 mg were associated with clinically relevant improvement in mean daily micturition (urination), urgency episodes, UUI episodes, OAB questionnaire symptom bother score, and proportion of patient global impression of change responders. Treatment-emergent adverse events occurred in 45.5% of patients receiving URO-902 24 mg, 46.2% receiving 48 mg, and 50.0%

receiving placebo. The most commonly occurring adverse event was urinary tract infection (0% in individuals receiving the 24 mg dose of URO-902; 15.4% in those receiving the 48 mg dose; and 3.8% in those receiving placebo). One patient in the 48 mg arm of the study had asymptomatic elevated post-void residual urine volume at week 2; this resolved spontaneously and did not require catheterization.

“URO-902 is a unique potential treatment for OAB. It brings together the accessibility of the anatomy of the condition with a new innovative approach to therapy,” said Sef Kurstjens, M.D., Ph.D., Executive Vice President and Chief Medical Officer of Urovant Sciences. Later this year, Urovant anticipates 48-week data from the Phase 2a trial, “at that point, we’ll have a greater sense of the durability of the therapy and our proposed next steps.”

The data were first presented earlier this year at the 2022 annual meeting of the American Urological Association (AUA2022) in New Orleans, La., from May 13-16, 2022.

About Overactive Bladder
Overactive bladder (OAB) is a clinical condition that occurs when the bladder muscle contracts involuntarily. Symptoms may include urinary urgency (the sudden urge to urinate that is difficult to control), urgency incontinence (unintentional loss of urine immediately after an urgent need to urinate), frequent urination (usually eight or more times in 24 hours), and nocturia (waking up more than two times in the night to urinate).[1]

While 33 million US adults experience the bothersome symptoms of OAB, approximately 546 million people ≥20 years are affected by OAB worldwide. [1,2]

About the Phase 2a Study of URO-902
The 48-week multicenter study was a randomized, double-blind, placebo-controlled trial to evaluate the efficacy, safety, and tolerability of a single physician administered dose of URO-902, a novel gene therapy being developed for patients with OAB who have not been adequately managed with oral or transdermal pharmacologic therapy. URO-902 is administered via direct intradetrusor injections into the bladder wall under local anesthesia in patients who are experiencing OAB symptoms and urge urinary incontinence (UUI).

The Phase 2a trial enrolled 80 female patients in two cohorts: the first cohort received either a single administration of 24 mg of URO-902 or matching placebo, and the second cohort received 48 mg of URO-902 or matching placebo into the bladder wall. Multiple outcome measures were explored, including the effect on the number of micturitions, urgency episodes, and quality-of-life indicators compared to placebo, 12 weeks post-administration, as well as an assessment of the safety and tolerability of this potential new therapy. Patients were followed for up to 48 weeks after initial administration.

About URO-902
URO-902 (*plasmid human cDNA encoding maxi-K channel)* has the potential to be the first gene therapy for patients with OAB. If approved, this innovative treatment has the potential to address an unmet need for patients who have failed oral pharmacologic therapies.

References:

1. Irwin DE, Kopp ZS, Agatep B, Milsom I, Abrams P. Worldwide prevalence estimates of lower urinary tract symptoms, overactive bladder, urinary incontinence and bladder outlet obstruction. *BJU Int*. 2011;108(7):1132-1138. doi:10.1111/j.1464-410X.2010.09993.x
2. Leron E, Weintraub AY, Mastrolia SA, Schwarzman P. Overactive bladder syndrome: evaluation and management. *Curr Urol*. 2017;11:117-125. doi:10.1159/000447205

About Urovant Sciences
Urovant Sciences is a biopharmaceutical company focused on developing and commercializing innovative therapies for areas of unmet need, with a dedicated focus in Urology. The Company's second product candidate, URO-902, is a novel gene therapy being developed for patients with OAB who have failed oral pharmacologic therapy. Urovant Sciences, a wholly-owned subsidiary of Sumitovant Biopharma Ltd., intends to bring innovation to patients in need in urology and other areas of unmet need.

About Sumitovant Biopharma
Sumitovant is a technology-driven biopharmaceutical company accelerating development of new potential therapies for patients with high unmet medical need. Through our subsidiary portfolio and use of embedded computational technology platforms to generate business and scientific insights, Sumitovant has supported development of FDA-approved products and advanced a promising pipeline of early- through late-stage investigational assets for other serious conditions. Sumitovant's subsidiary portfolio includes wholly-owned Enzyvant, Urovant, Spirovant, and Altavant, and one majority-owned subsidiary that is publicly listed: Myovant (NYSE: MYOV). Sumitomo Pharma is Sumitovant's parent company. For more information, please visit www.sumitovant.com.

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