Urovant Sciences® Presents Interim Data from Phase 2a Study of Investigational Novel Gene Therapy, URO-902, Supporting Safety, Tolerability, and Efficacy Endpoints at 2022 American Urological Association Meeting

May 14, 2022

- *Interim 12-week analysis from an ongoing Phase 2a trial of an investigational novel gene therapy product (plasmid human cDNA encoding maxi-K channel) showed clinically relevant improvement in the common symptoms of overactive bladder (OAB) compared to placebo. (Plenary Presentation PLLBA-03)*
- *In this prespecified 12-week analysis of a Phase 2a trial of women with OAB and urge urinary incontinence (UUI) who have failed oral therapies, a single dose of URO-902 24 mg or 48 mg was associated with clinically relevant improvement in efficacy and was well tolerated.*
- *The most common adverse event (24 mg URO-902/48 mg URO-902/placebo) was urinary tract infection (0%/15.4%/3.8%, respectively).*

IRVINE, Calif. and BASEL, Switzerland – May 13, 2022 – Urovant Sciences, a wholly owned subsidiary of Sumitovant Biopharma Ltd., announced that positive interim results from a Phase 2a trial of its investigational novel gene therapy, URO-902, were presented Friday at the 2022 annual meeting of the American Urological Association (AUA2022). The meeting is being held in New Orleans, from May 13-16, 2022.

Presented as a late-breaker during the plenary session, the interim results support that in women with OAB, not well managed by oral therapies, a single dose of URO-902 was safe and well tolerated. This was a prespecified, 12-week interim analysis of a 48-week multicenter, randomized, double-blind, placebo-controlled, dose-escalation study (NCT04211831). URO-902 was administered via direct intradetrusor injections via cystoscopy under local anesthesia.

"These positive findings indicate that URO-902 has the potential to be a new therapeutic option for overactive bladder patients who have failed oral pharmacologic therapy," said presenting author Kenneth Peters, MD, 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.

Of the 80 female patients who were randomized, 68 completed week 12 of the study and 74 were included in the intent-to-treat population. The mean age was 64.7 years.

At week 12, both URO-902 24 mg and 48 mg were associated with clinically relevant improvement compared with placebo 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.

"We are encouraged by these promising interim safety and efficacy findings for URO-902," said Sef Kurstjens, MD, PhD, Executive Vice President and Chief Medical Officer of Urovant Sciences. "This is in line with our ongoing efforts to develop innovative and effective treatments for patients in need."

The abstract is available in the *Journal of Urology* at the following link:

URO-902: https://www.auajournals.org/doi/10.1097/JU.0000000000002671.03

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 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.

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]

Approximately 30 million Americans suffer from bothersome symptoms of OAB, which can have a significant impairment on a patient's day-to-day activities.[1, 2]

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 lead product, GEMTESA ®(vibegron), is an oral, once-daily (75 mg) small molecule beta-3 agonist for the treatment of adult patients with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. GEMTESA was approved by the U.S. FDA in December 2020 and launched in the U.S. in April 2021. GEMTESA is also being evaluated for the treatment of OAB in men with benign prostatic hyperplasia. 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. Learn more about us at www.urovant.com or follow us on Twitter or LinkedIn.

About Sumitovant Biopharma

Sumitovant is a global biopharmaceutical company leveraging data-driven insights to rapidly accelerate development of new potential therapies for unmet patient conditions. Through our unique portfolio of wholly-owned "Vant" subsidiaries—Urovant, Enzyvant, Spirovant, Altavant—and use of embedded computational technology platforms to generate business and scientific insights, Sumitovant has supported the development of FDA-approved products and advanced a promising pipeline of early-through late-stage investigational assets for other serious conditions. Sumitovant, a wholly owned subsidiary of Sumitomo Pharma, is also the majority-shareholder of Myovant (NYSE: MYOV). For more information, please visit our website at www.sumitovant.com.

About GEMTESA®

GEMTESA is a prescription medicine for adults used to treat the following symptoms due to a condition called overactive bladder:

- urge urinary incontinence: a strong need to urinate with leaking or wetting accidents
- urgency: the need to urinate right away
- frequency: urinating often

It is not known if GEMTESA is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Do not take GEMTESA if you are allergic to vibegron or any of the ingredients in GEMTESA.

Before you take GEMTESA, tell your doctor about all your medical conditions, including if you have liver problems; have kidney problems; have trouble emptying your bladder or you have a weak urine stream; take medicines that contain digoxin; are pregnant or plan to become pregnant (it is not known if GEMTESA will harm your unborn baby; talk to your doctor if you are pregnant or plan to become pregnant); are breastfeeding or plan to breastfeed (it is not known if GEMTESA passes into your breast milk; talk to your doctor about the best way to feed your baby if you take GEMTESA).

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

What are the possible side effects of GEMTESA?

GEMTESA may cause serious side effects including the inability to empty your bladder (urinary retention). GEMTESA may increase your chances of not being able to empty your bladder, especially if you have bladder outlet obstruction or take other medicines for treatment of overactive bladder. Tell your doctor right away if you are unable to empty your bladder.

The most common side effects of GEMTESA include headache, urinary tract infection, nasal congestion, sore throat or runny nose, diarrhea, nausea, and upper respiratory tract infection. These are not all the possible side effects of GEMTESA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please click here for full Product Information for GEMTESA.

1. Reynolds, W. S., Fowke, J., & Dmochowski, R. (2016). The Burden of Overactive Bladder on US Public Health. Current bladder dysfunction reports, 11(1), 8–13. https://doi.org/10.1007/s11884-016-0344-9
2. Coyne, K. S., Sexton, C. C., Vats, V., Thompson, C., Kopp, Z. S., & Milsom, I. (2011). National community prevalence of overactive bladder in the United States stratified by sex and age. Urology, 77(5), 1081–1087.

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