Urovant Sciences to Present Interim Data from Phase 2a Study of Potential Novel Gene Therapy, URO-902, and New Analyses of Data from Phase 3 EMPOWUR Extension Trial of GEMTESA® (vibegron) 75 mg at 2022 American Urological Association Annual Meeting

April 13, 2022

- *Interim 12-week analysis from a Phase 2a trial of the potential gene therapy, URO-902, in women with overactive bladder (OAB) and urge urinary incontinence (UUI) will be featured in a late breaker presentation by Kenneth M. Peters, M.D. during Friday morning's plenary session.*
- *New analyses of data from the Phase 3 EMPOWUR Extension Study of GEMTESA® (vibegron) 75 mg will be presented during Sunday morning's podium session by:*
    - *Jeffrey Frankel, M.D., who will report on an analysis of long-term efficacy and safety in patients aged 65 years or above.*
    - *David Staskin, M.D., who will present an analysis of long-term patient-reported outcomes for OAB*

IRVINE, Calif. and BASEL, Switzerland – April 13, 2022 – Urovant Sciences, a wholly-owned subsidiary of Sumitovant Biopharma Ltd., announced that data from a Phase 2a trial of the investigational, novel gene therapy, URO-902, will feature as a late-breaker at the 2022 annual meeting of the American Urological Association (AUA2022), May 13-16, in New Orleans, Louisiana. The plenary presentation will include interim efficacy and safety data on URO-902 from the ongoing Phase 2a trial.

In addition, two podium presentations at AUA2022 will feature new analyses of data from the EMPOWUR 40-week extension trial of GEMTESA® (vibegron) 75 mg, a Phase 3, randomized, double blind, active-comparator controlled multicenter study to evaluate long-term safety and efficacy in patients with symptoms of OAB. GEMTESA is approved by the U.S. Food and Drug Administration (FDA) for the treatment of OAB in adults with symptoms of UUI, urgency, and urinary frequency.

"Overactive bladder remains a condition in need of additional treatment options. We look forward to sharing new data related to the use of GEMTESA in the OAB patient population as well as providing an initial read-out on the progress of our investigational gene therapy, URO-902," said Sef Kurstjens, M.D., Ph.D., Executive Vice President and Chief Medical Officer of Urovant Sciences. "We believe that URO-902 could potentially offer a new treatment option for patients with overactive bladder who have been inadequately managed by oral pharmacologic therapy, if approved by the FDA. The two podium presentations on GEMTESA will also add to the scientific and medical community's understanding of this important therapy."

Data on the potential novel gene therapy, URO-902, will be presented during Friday morning's plenary session:

Late-Breaking Abstract PLLBA-03, presented by Kenneth M. 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, Michigan., titled, "Efficacy and Safety of a Novel Gene Therapy (URO-902; pVAX/ *hSlo*) in Female Patients with Overactive Bladder and Urge Urinary Incontinence: Results from a Phase 2a Trial." This presentation will take place on Friday, May 13, at 11:21 to 11:29 a.m. CDT during the plenary session in the Ernest N. Morial Convention Center, Great Hall A.

Data on GEMTESA will also be featured in two podium presentations at the conference on May 15, 2022:

- PD38-11: "'Long-Term Efficacy and Safety of Vibegron for Overactive Bladder in Patients ≥65 Years Old: Analysis from the EMPOWUR Extension Trial,"' to be presented by Jeffrey Frankel, M.D., Medical Director, Seattle Urology Research Center, Seattle, Washington. (8:40 to 8:50 a.m. CDT in the Ernest N. Morial Convention Center, Room 244)

- PD38-12: "'Long-Term Patient-Reported Outcomes of Vibegron for Overactive Bladder: Analyses from the EMPOWUR Extension Trial,"' to be presented by David Staskin, M.D., Associate Professor of Urology, Tufts University School of Medicine. (8:50 to 9:00 a.m. CDT in the Ernest N. Morial Convention Center, Room 244)

Abstracts are available in the *Journal of Urology* at the following links:

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

EMPOWUR-EXT older adults: https://www.auajournals.org/doi/10.1097/JU.0000000000002596.11

EMPOWUR-EXT PRO: https://www.auajournals.org/doi/10.1097/JU.0000000000002596.12

About the Phase 2a Study of URO-902

This 48-week multicenter, randomized, double blind, placebo-controlled, dose-escalation study will evaluate the efficacy, safety, and tolerability of a single administration of URO-902, a novel gene therapy being developed for patients with OAB who have failed oral pharmacologic therapy. URO-902 is administered via direct intradetrusor injections via cystoscopy into the bladder wall under local anesthesia in patients who are experiencing OAB symptoms and UUI.

The Phase 2a trial includes 80 female patients in two cohorts. The first cohort received either a single administration of 24 mg of URO-902 or matching placebo into the bladder wall, and the second cohort received 48 mg of URO-902 or matching placebo into the bladder wall. Patients will be followed for up to 48 weeks after initial administration. Exploratory endpoints included change from baseline to week 12 in mean daily micturitions, urgency episodes, UUI episodes, and quality of life measures, as well as assessing the safety and tolerability of this investigational gene therapy for OAB.

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 the EMPOWUR Trial

The EMPOWUR trial was an international, randomized, double-blind, placebo and active comparator-controlled Phase 3 clinical trial evaluating the safety and efficacy of investigational vibegron in men and women with symptoms of overactive bladder, including frequent micturition, urgency, and UUI. A total of 1,518 patients were randomized across 215 study sites into one of three groups for a 12-week treatment period with a four-week safety follow-up period: vibegron 75 mg administered orally once daily; placebo administered orally once daily; or tolterodine ER 4 mg administered orally once daily.

About the 40-Week EMPOWUR Extension

The EMPOWUR 40-week extension trial was a Phase 3, randomized, double blind, active-comparator controlled multicenter study to evaluate the long-term safety and efficacy of vibegron in patients with symptoms of overactive bladder. The extension study enrolled approximately 500 EMPOWUR completers. The primary endpoint was safety, measured by incidence of adverse events. Secondary endpoints were changes from EMPOWUR baseline at week 52 in average daily micturitions, UUI, urgency, and total urinary incontinence.

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 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.

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

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