Urovant Sciences® presents new data from EMPOWUR study, advancing knowledge of the treatment of overactive bladder at the 2022 American Urological Association Meeting

May 15, 2022 at 9:05 a.m. CDT

- *New analyses of data from the Phase 3 EMPOWUR Extension Study of GEMTESA® (vibegron) 75 mg provided additional insight into the long-term effects of the product. These data were featured in podium presentations PD 38-11 and PD 38-12:*
  - *In a subgroup analysis of adults, 65 years old or above with overactive bladder, treatment with GEMTESA was safe and well tolerated. Treatment with GEMTESA was associated with sustained reductions from baseline in average daily micturition, urge urinary incontinence (UUI) episodes and urgency episodes. These results were consistent with the overall EMPOWUR study population (PD 38-11).*
  - *GEMTESA at 52 weeks was associated with sustained and patient-perceived meaningful improvements in both the OAB questionnaire (OAB-q) and Patient Global Impression (PGI) scores in the EMPOWUR extension trial (PD 38-12).*

IRVINE, Calif. and BASEL, Switzerland – May 15, 2022 – Urovant Sciences, a wholly owned subsidiary of Sumitovant Biopharma Ltd., announced new analyses from the Phase 3 EMPOWUR Extension Study of GEMTESA, presented Sunday at the 2022 annual meeting of the American Urological Association (AUA2022). The meeting is being held in New Orleans from May 13-16, 2022.

"The additional analyses of data on our overactive bladder therapy, GEMTESA, further confirm this drug's potential utility and durability in this patient population," said Sef Kurstjens, MD, PhD, Executive Vice President and Chief Medical Officer of Urovant Sciences. "This is an additional demonstration of Urovant's commitment to providing effective therapies for patients with urologic conditions."

Two podium presentations at AUA2022 on May 15 featured new analyses of data from the EMPOWUR 40-week extension trial of GEMTESA (vibegron) 75 mg. This was a Phase 3, randomized, double-blind, active-comparator controlled, parallel-group 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 for the treatment of OAB symptoms of UUI, urgency, and urinary frequency in adults.

The first podium presentation, PD38-11, presented at 8:40-8:50 a.m. by Jeffrey Frankel, MD, Medical Director, Seattle Urology Research Center, Seattle, Washington, is titled, "Long-Term Efficacy and Safety of Vibegron for Overactive Bladder in Patients ≥65 Years Old: Analysis from the EMPOWUR Extension Trial." In a subgroup analysis of adults, 65 years old or above with overactive bladder, treatment with GEMTESA was safe and well tolerated. Treatment with GEMTESA was associated with sustained reductions from baseline in average daily micturition, UUI episodes, and urgency episodes. These results were consistent with the overall EMPOWUR Extension Study population.

The second podium presentation, PD38-12, presented at 8:50-9:00 a.m. by David Staskin, MD, Associate Professor of Urology, Tufts University School of Medicine, is titled, "Long-Term

Patient-Reported Outcomes of Vibegron for Overactive Bladder: Analyses from the EMPOWUR Extension Trial." This analysis of data from the EMPOWUR Extension Trial supports that patient-perceived meaningful improvements in OAB questionnaire (OAB-q) and Patient Global Impression (PGI) scores were consistent with GEMTESA's improvements in OAB symptoms and a favorable safety and tolerability profile during the 52-week treatment period.

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

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.

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.

Urovant Sciences
Alana Darden Powell
Vice President, Corporate Communications
949-436-3116
alana.darden@urovant.com
media@urovant.com

Sumitovant Biopharma
Maya Frutiger
Head of Corporate Communications
media@sumitovant.com

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