Urovant Sciences Presents Positive Ambulatory Blood Pressure Data Showing That GEMTESA® (vibegron) 75 mg in Overactive Bladder Was Not Associated with Statistically Significant or Clinically Meaningful Effects on Blood Pressure or Heart Rate

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- *New data from dedicated ambulatory blood pressure study of patients with overactive bladder (OAB) showed once-daily treatment with GEMTESA® was not associated with statistically significant or clinically meaningful effects on blood pressure or heart rate*
- *Phase 3 EMPOWUR trial post-hoc subgroup analyses showed once-daily GEMTESA was associated with significantly reduced daily urgency episodes and micturitions in patients with OAB wet and dry (with and without urge urinary incontinence [UUI] per diary day, respectively) vs. placebo*
- *Presented at the virtual AUA 2021 annual meeting, these data further support safety and efficacy of GEMTESA for treatment of OAB in patients with symptoms of UUI, urgency, and urinary frequency*

IRVINE, Calif. and BASEL, Switzerland – (BUSINESS WIRE) – Urovant Sciences, Inc., a wholly-owned subsidiary of Sumitovant Biopharma Ltd., today presented data on GEMTESA® (vibegron) 75 mg in patients with overactive bladder (OAB) at the 2021 Annual Meeting of the American Urological Association (AUA) held virtually from September 10-13, 2021.

“We are delighted to present these important additional data confirming the efficacy and safety profile of GEMTESA,” said Cornelia Haag-Molkenteller, MD, PhD, Chief Medical Officer of Urovant Sciences. “The data from the ambulatory blood pressure study demonstrating no statistically significant or clinically relevant effect on blood pressure with GEMTESA, a beta-3 agonist to treat OAB, will be important for physicians and patients suffering from OAB.”

In a randomized, double-blind study of patients with OAB, once-daily treatment with GEMTESA was not associated with statistically significant or clinically meaningful effects on blood pressure or heart rate. The study was described in a virtual podium presentation (#PD66) by Michael A. Weber, MD, Professor of Medicine at the State University of New York Downstate College of Medicine, Brooklyn, NY. The presentation was entitled, “Effects of Vibegron on Ambulatory Blood Pressure in Patients with Overactive Bladder: Results from a Double-Blind Study.”

“This standalone study was conducted to understand the potential effects of GEMTESA on heart rate and blood pressure in a dedicated study using ambulatory blood pressure measurements,” said Dr. Weber. “The new data confirm that GEMTESA has no statistically significant or clinically relevant impact on blood pressure compared to placebo.”

Results from Ambulatory Blood Pressure Study
The ambulatory blood pressure study enrolled 214 patients with OAB, aged between 40-75 years. The mean age was 59.3 years and 74.6% of all patients were female. Overall, 35% of patients had pre-existing hypertension, which was present in slightly more patients in the GEMTESA group than in the placebo group. Demographic characteristics were well balanced between the groups.

The primary endpoint was change from baseline to day 28 in mean daytime ambulatory systolic blood pressure and was evaluated against a criterion of 3.5 mmHg for the upper limit of the confidence interval. Key secondary endpoints were change from baseline to day 28 in mean daytime ambulatory diastolic blood pressure and heart rate and change from baseline to day 28 in mean 24-hour ambulatory systolic blood pressure, diastolic blood pressure, and heart rate. Safety was assessed through adverse event reporting and safety lab tests.

Individuals with valid 24-hour ambulatory blood pressure readings at baseline were randomly assigned 1:1 to receive once daily GEMTESA or placebo for 28 days. At day 28, patients returned to the clinic for a second 24-hour assessment. At baseline, in-clinic mean baseline systolic blood pressure, diastolic blood pressure, and heart rate were generally similar between groups. There were no statistically significant or clinically relevant differences in mean daytime or mean 24-hour ambulatory systolic blood pressure, diastolic blood pressure, or heart rate after 28 days of treatment with GEMTESA compared with placebo.

Serious treatment-emergent adverse events occurred in 1 patient in each group (GEMTESA: postoperative pain; placebo: hypoglycemia). Hypertension was the most frequently reported treatment-emergent adverse event in both the placebo (4 patients) and the GEMTESA treatment group (5 patients); however, no event of hypertension with GEMTESA was considered related to study treatment. Of the 5 reported events of hypertension with GEMTESA, 1 occurred in a patient taking phentermine, which was a prohibited medication as it is known to increase blood pressure.

EMPOWUR Subgroup Analyses
Post hoc subgroup analyses of data from the international, randomized, placebo- and active-controlled Phase 3 EMPOWUR trial were the subject of a virtual poster presentation (#MP63) by David Staskin, MD. The principal investigator of the EMPOWUR study, Dr. Staskin is a urologist with St. Elizabeth’s Medical Center, and Associate Professor of Urology at Tufts University School of Medicine, Boston. The virtual poster was entitled, “Vibegron for the Treatment of Patients with Dry Overactive Bladder: A Subgroup Analysis from the EMPOWUR Trial.”

“The data from the subgroup analyses indicate that compared with placebo, once-daily GEMTESA 75 mg was associated with significant reductions in daily urgency episodes and urinary frequency also in patients with OAB who did not have urinary urge incontinence,” said Dr. Staskin. “These positive effects were seen in patients with OAB wet, who have urinary incontinence, and OAB dry, who do not. This suggests that GEMTESA is similarly effective for these endpoints in patients with OAB wet and dry.”

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 urination, sudden urge to

urinate, and urge incontinence or leakage. 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 extended release (ER) 4 mg administered orally once daily.

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).2
Approximately 30 million Americans suffer from bothersome symptoms of OAB, which can have a significant impairment on a patient's day-to-day activities.2, 3

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 urologic conditions. 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 develop novel treatments for additional urologic diseases. Learn more about us at www.urovant.com.

About Sumitovant Biopharma Ltd.
Sumitovant is a global biopharmaceutical company with offices in New York City and London. Sumitovant is the majority shareholder of Myovant (NYSE: MYOV) and wholly-owns Urovant, Enzyvant, Spirovant, and Altavant. Sumitovant's promising pipeline is comprised of early-through late-stage investigational medicines across a range of disease areas targeting high unmet need. Sumitovant is a wholly-owned subsidiary of Sumitomo Dainippon Pharma. For further information about Sumitovant, please visit https://www.sumitovant.com.

About Sumitomo Dainippon Pharma Co., Ltd.
Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China, and the European Union. Sumitomo Dainippon Pharma is based on the 2005 merger between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has more than 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at https://www.ds-pharma.com.

To read our news release, visit urovant.com/news-releases.

1. Staskin, D., Frankel, J., Varano, S., Shortino, D., Jankowich, R., Mudd, P.N. Jr. International Phase III, Randomized, Double-Blind, Placebo and Active Controlled Study to Evaluate the Safety and Efficacy of Vibegron in Patients with Symptoms of Overactive Bladder: EMPOWUR. J Urol. 2020 Aug;204(2):316-324. doi: 10.1097/JU.0000000000000807. Epub 2020 Feb 18. PMID: 32068484.
2. 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
3. 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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