Urovant Sciences Announces Publication in Blood Pressure Monitoring of Positive Ambulatory Blood Pressure Study Results for GEMTESA® (vibegron) 75 mg in Overactive Bladder Patients

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- *Data from a dedicated ambulatory blood pressure study showed once-daily treatment with GEMTESA® was not associated with statistically significant or clinically meaningful effects on blood pressure or heart rate*

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Nov. 8, 2021-- Urovant Sciences, Inc., a wholly- owned subsidiary of Sumitovant Biopharma Ltd., announced today that the journal *Blood Pressure Monitoring* has published the ambulatory blood pressure data on its recently-approved overactive bladder (OAB) therapy, GEMTESA® (vibegron) in the U.S. The peer-reviewed publication is currently available online and the print article is scheduled to be published in an upcoming issue of the journal.

In a dedicated, double-blind, placebo-controlled ambulatory blood pressure study of patients with OAB, once-daily treatment with GEMTESA® 75 mg was not associated with statistically significant or clinically meaningful effects on blood pressure or heart rate. The article is entitled, “Effects of Vibegron on Ambulatory Blood Pressure in Patients with Overactive Bladder: Results from a Double-Blind, Placebo-Controlled Trial.”

"The publication of this dedicated ambulatory blood pressure study in OAB patients in a peer-reviewed cardiology journal further supports the safety profile of GEMTESA," said co-author Cornelia Haag-Molkenteller, MD, PhD, executive vice president and Chief Medical Officer of Urovant Sciences. "GEMTESA does not have a blood pressure warning in its label, which is an important consideration for health care providers and patients.”

"This standalone study was carried out to understand the potential effects of GEMTESA on heart rate and blood pressure based on ambulatory blood pressure measurements," said lead author Michael A. Weber, MD, Professor of Medicine at the State University of New York Downstate College of Medicine, Brooklyn, NY. “The published data substantiate that compared with placebo, GEMTESA has no statistically significant or clinically meaningful impact on blood pressure."

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 after completion of 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 meaningful 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 known to increase blood pressure.

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 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 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 Dainippon Pharma, is also the majority-shareholder of Myovant (NYSE: MYOV). For more information, please visit our website at www.sumitovant.com or follow us on Twitter and LinkedIn.

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 other Asian countries. 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. 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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