Urovant Sciences Announces Publication in Advances in Therapy of Analyses of Patient-Perceived Meaningfulness of Improvement in Symptom Reduction for Overactive Bladder Patients Treated with GEMTESA® (vibegron) 75 mg

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- *Data from the 12-week EMPOWUR trial regarding patient perceptions of improvement of OAB symptoms show that significantly more patients treated once-daily with GEMTESA® (vibegron) experienced patient-perceived improvements due to the reduction in micturition frequency (urination), urinary urgency episodes, and urge urinary incontinence episodes vs. placebo.*
- *This analysis supports that the statistically significant reductions in clinical endpoints seen in the EMPOWUR trial are meaningful to patients.*

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Dec. 20, 2021-- Urovant Sciences, Inc., a wholly-owned subsidiary of Sumitovant Biopharma Ltd., announced today that the journal *Advances in Therapy* has published patient-perception data supporting clinical meaningfulness of overactive bladder (OAB) symptom reduction for its FDA-approved OAB therapy, GEMTESA® (vibegron), compared to placebo. The article entitled, "*Interpretation of the Meaningfulness of Symptom Reduction with Vibegron in Patients with Overactive Bladder: Analyses from EMPOWUR*" is available online and the print version will be published in an upcoming issue of the journal.

The analysis of 12-week data from the EMPOWUR study regarding patient perception supports that the reductions in OAB symptoms such as urinary frequency, urgency, and urinary incontinence were meaningful to patients after treatment with GEMTESA 75 mg compared with those receiving placebo. These data also were presented at sectional American Urological Association (AUA) and Urology-focused meetings this fall including SCS-AUA, NCS-AUA, ICS, NE-AUA, SUNA, and WS-AUA.

"Our findings suggest that the statistically significant improvements in bothersome symptoms of OAB seen in the 12-week EMPOWUR trial are indeed clinically relevant in terms of patient perceptions," said lead author Jeffrey Frankel, MD, of Seattle Urology Research Center. "These significantly higher proportions of patients achieving pre-defined patient-perceived symptom improvements are likely to inform patients and providers in establishing realistic treatment goals."

"The patient-centered analysis further supports that GEMTESA is an important treatment option with meaningful clinical benefit for patients with OAB," said Cornelia Haag-Molkenteller, MD, PhD, executive vice president and Chief Medical Officer of Urovant Sciences. "The publication in a peer-reviewed journal is another example of Urovant's commitment to informing the scientific – medical community about meaningful effects of GEMTESA."

About the Analysis

Although OAB is highly prevalent among adults; large clinical studies often neglect to report patient perceptions of the meaningfulness of symptom improvement. The new publication describes a method to derive meaningful within-patient change using a patient-reported measure, the Patient Global Impression of Change (PGI-C). Based on patient interviews and PGI-C results applied to phase 2 and 3 studies, the authors established responder-based definitions of clinically meaningful improvement in reducing micturitions, urgency episodes, and UUI episodes. This analysis indicated that significantly more patients receiving vibegron vs. placebo achieved meaningful responder definitions: ≥15 percent reduction in micturitions (56.3 vs. 44.6 percent, respectively) (post hoc), ≥50 percent reduction in urgency episodes (39.5 vs. 32.8 percent), ≥75 percent reduction in UUI episodes (49.3 vs. 32.8 percent), and ≥90 percent reduction in UUI episodes (35.2 vs. 23.5 percent) (post hoc) at week 12 (P<0.05 each).

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.

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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