Urovant Sciences Announces Publication of EMPOWUR Trial Subgroup Analysis Showing Similar Efficacy for GEMTESA® (Vibegron) 75mg in Dry and Wet Overactive Bladder Populations

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- *Post-hoc analysis indicates significant reductions in urgency episodes and micturitions in patients treated with GEMTESA vs. placebo in both types of overactive bladder (OAB)*
- *Article appears in the peer-reviewed International Journal of Clinical Practice*
- *Findings are consistent with overall data from the EMPOWUR study, showing favorable efficacy in patients with OAB, and published previously in the Journal of Urology*

IRVINE, Calif. & BASEL, Switzerland – April 19, 2022 – Urovant Sciences, a wholly-owned subsidiary of Sumitovant Biopharma Ltd., today announced the publication of a new, post-hoc analysis of data from the Phase 3 EMPOWUR trial of GEMTESA (vibegron) 75 mg in the *International Journal of Clinical Practice*. The peer-reviewed paper is entitled, "Vibegron for the Treatment of Patients with Dry and Wet Overactive Bladder: A Subgroup Analysis from the EMPOWUR Trial." The article is available online and will be published in an upcoming print issue of the journal.

OAB is characterized by urgency and frequency with (OAB wet) or without (OAB dry) urge urinary incontinence (UUI). Although OAB dry affects a larger proportion of the OAB population, studies of pharmacologic treatment typically report results in the overall OAB population or in patients with OAB wet. They also commonly focus on UUI as the most bothersome symptom of OAB. As a result, treatment guidelines do not differentiate between these patients and often neglect to address the need to manage the disruptive and core symptom of urgency associated with OAB. The post-hoc analysis was developed to compare efficacy of vibegron vs. placebo in OAB wet and dry populations.

"In this subgroup analysis of data from the EMPOWUR trial, vibegron was associated with significant reductions in urgency episodes and micturitions (urination) compared with placebo in both the OAB dry and wet populations," said lead author Jeffrey Frankel, MD, Medical Director, Seattle Urology Research Center. "This indicates that vibegron may be similarly efficacious in improving these endpoints in patients with and without urge urinary incontinence."

These findings are consistent with overall EMPOWUR data showing favorable long-term safety, tolerability and efficacy in patients with overactive bladder; these were published in the *Journal of Urology* in May 2021.[1]

In the EMPOWUR study, patients were randomly assigned 5:5:4 to receive once-daily vibegron 75 mg, placebo, or tolterodine 4 mg extended release, respectively, for 12 weeks. Serious adverse events associated with vibegron occurred at rates comparable with placebo (1.5 vs 1.1 percent for vibegron vs. placebo, respectively) in EMPOWUR; the most frequently occurring treatment-emergent adverse events (TEAEs) with incidence greater for vibegron than placebo were headache and nasopharyngitis. Hypertension incidence was similar between vibegron and placebo treatment groups.

"This latest publication further confirms GEMTESA's role as a helpful treatment option for both OAB-dry and OAB-wet patient types, making it an important option for people living with OAB," said Salim Mujais, Senior Vice President Clinical Development, Urovant Sciences. "This condition affects an estimated 30 million Americans and can have an impact on activities of daily living. Clinically meaningful decreases in urinary urgency may address an unmet need in these patients."

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 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).[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],[ii]

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 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 Pharma, is also the majority-shareholder of Myovant (NYSE: MYOV). For more information, please visit our website at www.sumitovant.com.

About Sumitomo Pharma Co., Ltd.

Sumitomo 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 with more than 7,000 employees worldwide. Sumitomo Pharma defines its corporate mission as "To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide." Additional information about Sumitomo Pharma is available through its corporate website at https://www.sumitomo-pharma.com.

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