Urovant Sciences Announces Publication of New Review of Efficacy and Safety Data for GEMTESA® (vibegron) 75 mg in Overactive Bladder Patients in the Journal Therapeutics and Clinical Risk Management

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- *Review article in a peer-reviewed journal examines studies of GEMTESA published in the past 3 years*
- *Data support GEMTESA's role as an effective treatment option for overactive bladder (OAB) based on studies including:*
  - *Two phase 3 trials (EMPOWUR, EMPOWUR extension) conducted with once daily vibegron 75 mg for the treatment of OAB*
  - *Additional secondary and subgroup analyses of EMPOWUR and EMPOWUR extension*
  - *A separate, dedicated ambulatory blood pressure monitoring study showing that treatment with vibegron was not associated with clinically meaningful effects on blood pressure or heart rate*
- *Across all studies, vibegron was efficacious, safe, and well tolerated.*

IRVINE, Calif. & BASEL, Switzerland – March [22], 2022 – Urovant Sciences, a wholly-owned subsidiary of Sumitovant Biopharma Ltd., today announced the publication of a new review of data on GEMTESA (vibegron) 75 mg in the peer-reviewed journal, *Therapeutics and Clinical Risk Management* (https://bit.ly/Vibegron). Titled, 'An evaluation of the efficacy and safety of vibegron in the treatment of overactive bladder,' the paper reviews published data from studies conducted over the past three years.

"This new review highlights the fact that across all studies, vibegron was efficacious, safe and well tolerated, and is an option for the treatment of patients with overactive bladder, including older adults," said lead author Jeffrey Frankel, MD, of Seattle Urology Research Center. "This product offers a promising alternative to anticholinergics, with a clinically meaningful impact for patients.

"Over a year after GEMTESA's approval in the United States, this data further underscore vibegron's potential clinical benefit for patients with OAB," said Cornelia Haag-Molkenteller, MD, PhD, executive vice president and Chief Medical Officer of Urovant Sciences.

The *Therapeutics and Clinical Risk Management* paper points out that in the international phase 3 EMPOWUR trial, treatment with GEMTESA was associated with significant improvements compared with placebo in the efficacy outcomes of micturition frequency, urge urinary incontinence (UUI) episodes, urgency episodes, and volume voided. The 40-week EMPOWUR extension study evaluated safety in patients receiving GEMTESA for 52 weeks. Treatment with GEMTESA was also associated with improvements in patient-reported outcomes.

Serious adverse events (AEs) occurred at rates comparable with placebo (1.5% vs 1.1% for vibegron vs placebo, respectively) in EMPOWUR and with active control (3.3% vs 4.3% for vibegron vs active control, respectively) in the EMPOWUR extension study. In EMPOWUR, the most frequently occurring treatment-emergent AEs (TEAEs) with incidence greater for vibegron than placebo were headache and nasopharyngitis. Hypertension incidence was similar between vibegron and placebo treatment groups. In the EMPOWUR extension study, the most common TEAEs with vibegron were hypertension (incidence similar to active control), urinary tract infection and headache.

A separate, dedicated ambulatory blood pressure monitoring study showed that treatment with vibegron, similar to placebo, was not associated with clinically meaningful effects on blood pressure or heart rate. In this study, the most frequently occurring TEAEs with vibegron were hypertension, upper respiratory tract infection and headache.

Improvements in patient-reported outcomes suggest that vibegron achieves both objective measures of clinical efficacy and subjective measures of symptomatic improvement that may be perceived as more meaningful by patients, according to the paper.

The paper concludes that further investigation into the real-world effectiveness of vibegron is warranted based on the promising efficacy and safety data seen in clinical trials.

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 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 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.

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