Urovant Sciences Announces Publication of Pharmacokinetic Data on GEMTESA® (Vibegron 75mg) Administered as an Intact or Crushed Tablet

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- A new peer-reviewed journal paper suggests that **crushing GEMTESA (vibegron) 75-mg and taking it with applesauce may be an appropriate option for people with overactive bladder (OAB) and concomitant swallowing difficulties.**
- Results from this Phase 1 study show that vibegron can be crushed and mixed with applesauce with **no clinically meaningful change to pharmacokinetic (PK) parameters or stability. GEMTESA was stable over 4 hours after crushing and mixing in applesauce.**
- In the study, 30 participants were randomized, and 29 were included in the pharmacokinetic (PK) analysis. Patients were randomly assigned to one of two sequences for vibegron formulation administration, ensuring all patients received both an intact and a crushed tablet by study completion.
- Adverse events (AEs) were reported in 16 participants (53.3%); Treatment emergent adverse events (TEAEs) occurred in 9 (30.0%) participants. The most common TEAE was headache in 4 (13.3%) participants. There were no study discontinuations due to TEAEs.

IRVINE, Calif. & BASEL, Switzerland – October 27, 2022 – Urovant Sciences, a wholly-owned subsidiary of Sumitovant Biopharma Ltd., today announced the recent publication of a Phase 1 study of the pharmacokinetic profile of GEMTESA (vibegron) 75mg in the peer-reviewed journal, *Clinical Pharmacology in Drug Development*. In the study, which involved healthy adults, GEMTESA was administered in a single 75-mg dose as an intact tablet vs. crushed and mixed with applesauce. The results suggest that crushing and administering vibegron with applesauce may be an appropriate consideration for patients with overactive bladder (OAB) and swallowing difficulties.

The paper is titled, “Pharmacokinetics and Safety of Vibegron 75 mg Administered as an Intact or Crushed Tablet in Healthy Adults.”

“The fact that GEMTESA can be crushed and given with applesauce suggests potential for use in older patients, particularly those in the long-term care setting, given the prevalence of both OAB and swallowing difficulties increase with age,” said Sef Kurstjens, M.D., Ph.D., Executive Vice President and Chief Medical Officer of Urovant Sciences. “This aligns with Urovant’s goal of developing and commercializing OAB treatment options tailored to meet different administration needs.”

The authors of the publication note that “Many patients, particularly those who are older, have difficulty swallowing an intact tablet, which may be due to physiologic changes, tablet size, or both. Consequently, older patients may skip taking their medications or may take their medication in a nonprescribed method.” The authors write that “the lack of apparent clinically meaningful differences with vibegron upon crushing and administration is particularly important because few oral pharmacotherapies for OAB retain their essential properties when crushed.”

In the newly published Phase 1 study, 30 participants were randomized, with 29 being included in the analysis. All patients received one treatment with intact tablet and one with crushed tablet, mixed with applesauce. Primary endpoints included single dose PK parameters of C_{max} and AUC from time 0 to the last measurable concentration-time curve ($AUC_{0\text{-}t}$ and $AUC_{0\text{–}\infty}$). Two measures of the plasma concentration-time profile of GEMTESA when crushed and mixed with applesauce (C_{max} and $AUC_{0\text{–}\infty}$)

showed decreases. These were not considered clinically significant based on earlier Phase 2 results that indicated continued efficacy at these lower levels.

Additional secondary endpoints included safety, perception of taste, stability, and assessment of additional plasma PK parameters:

- ***Safety*** was assessed by the number of TEAEs, which were reported in 16 participants (53.3%) (crushed, 12 (43.3%); intact 9 (30.0%). GEMTESA was well tolerated with the most common TEAE reported being headache crushed, 7 (13.3%); intact, 6 (13.3%). Additional reported TEAEs experienced by ≥2 participants were constipation (crushed, 13.3%; intact 6.7%) and nausea (crushed 6.7%,intact 0%) .
- ***Perception of taste*** was assessed via a questionnaire, with about one-half (53.3%) of participants reporting that the GEMTESA and applesauce mixture tasted as expected. Of those who said the taste was different than expected 7 (50%) described the taste as "bitter," and 80% of patients disliked the taste. There were no study discontinuations due to taste.
- ***Stability measures*** indicated that GEMTESA was stable for 4 hours in applesauce.
- ***Assessment of additional plasma PK parameters*** included several secondary endpoints: time to C_{max}, terminal half-life, total clearance following oral administration, volume of distribution at terminal phase following oral administration, and safety and tolerability parameters such as AEs, and clinical laboratory and vital sign assessments. Plasma vibegron concentration-time data were also analyzed.

GEMTESA is approved by the U.S. Food and Drug Administration for adults in the treatment of OAB symptoms of urge urinary incontinence (UUI), urgency, and urinary frequency.

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 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. Named one of the Fortune® Best Workplaces

in BioPharma™ (2022), twice as one of the "Best Places to Work" in Orange County by the Orange County Business Journal (2021, 2022) and winner of the PM360 Trailblazer Award for Best Product Launch of the Year, Urovant's people-focused culture leads the way for innovation and impact. Learn more about Urovant at www.Urovant.com or follow on Twitter, Linked In or Instagram.

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 Sumitovant Biopharma
Sumitovant is a technology-driven biopharmaceutical company accelerating development of new potential therapies for patients with high unmet medical need. Through our subsidiary portfolio and use of embedded computational technology platforms to generate business and scientific insights, Sumitovant has supported development of FDA-approved products and advanced a promising pipeline

of early-through late-stage investigational assets for other serious conditions. Sumitovant's subsidiary portfolio includes wholly-owned Enzyvant, Urovant, Spirovant and Altavant, and majority-owned Myovant (NYSE: MYOV). Sumitomo Pharma is Sumitovant's parent company. For more information, please visit www.sumitovant.com.

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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