



## Urovant Sciences Announces U.S. FDA Approval of GEMTESA® (vibegron) 75 mg Tablets for the Treatment of Patients with Overactive Bladder (OAB)

December 23, 2020

*GEMTESA is the first new oral branded OAB medication approved by the U.S. FDA since 2012 and the first product approval for Urovant Sciences*

*U.S. commercial launch planned in late-Q1 2021*

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Dec. 23, 2020-- Urovant Sciences (Nasdaq: UROV) announced today that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for once-daily 75 mg GEMTESA® (vibegron), a beta-3 adrenergic receptor ( $\beta_3$ ) agonist, for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence (UUI), urgency, and urinary frequency in adults. This approval marks the first new oral branded OAB medication approved by the FDA since 2012, and it is the first product approval for Urovant Sciences.

"The FDA's approval of GEMTESA is an important milestone for the tens of millions of patients living with overactive bladder and for Urovant, as it is our first drug approval. We look forward to launching GEMTESA in the coming months and believe that it will provide a compelling alternative for the many patients suffering from the burden of an overactive bladder. We also remain committed to bringing more new therapies to market that address unmet medical needs of patients suffering from urologic diseases," said Jim Robinson, president and chief executive officer of Urovant Sciences.

"The clinical data for once-daily 75 mg GEMTESA demonstrated clear efficacy on the key symptoms of OAB by reducing urinary frequency, urge urinary incontinence, and urgency. In addition, data specifically showing reduction in urgency episodes are included in the Prescribing Information of GEMTESA, which is unique among currently-available OAB treatments. Urgency episode reduction data are particularly relevant for OAB patients and their health care providers, as they show GEMTESA's direct impact on a hallmark symptom of the condition," said Cornelia Haag-Molkenteller, M.D., Ph.D., chief medical officer of Urovant Sciences. "By successfully treating clinical symptoms, GEMTESA may allow patients to overcome the devastating impact that OAB can have on their daily lives."

GEMTESA is an oral, once-daily tablet containing 75 mg of vibegron, a small-molecule  $\beta_3$  agonist which helps relax the detrusor bladder muscle so that the bladder can hold more urine, thereby reducing symptoms of OAB.

"GEMTESA is the first beta 3-agonist available as a once-daily pill which does not require dose titration," said David Staskin, MD, clinical trial investigator and a leading urologist with St. Elizabeth's Medical Center in Boston. "Notably, GEMTESA did not have any increase in the adverse event of hypertension compared to placebo in the key EMPOWUR study and has no interactions with medications metabolized by CYP2D6, which is important since many common medications are metabolized by CYP2D6."

The FDA's approval is based on results from an extensive development program involving more than 4,000 OAB patients, including the 12-week double blind, placebo-controlled Phase 3 EMPOWUR study with a dose of 75 mg and the double blind EMPOWUR long term extension study.<sup>1</sup> These data show that treatment with GEMTESA resulted in statistically significant reductions in daily UUI, micturitions, and urgency episodes and an increase in the volume voided when compared to placebo in EMPOWUR.

The most common adverse reactions of GEMTESA from the double blind, placebo-controlled EMPOWUR study in  $\geq 2\%$  of patients were headache, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection. GEMTESA demonstrated the same rates for the adverse events of hypertension and increased blood pressure as placebo.

Urovant is planning to launch GEMTESA in the United States late in the first quarter of 2021. To learn more about GEMTESA, please visit [GEMTESA.com](http://GEMTESA.com).

### About 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).<sup>2</sup>

More than 30 million Americans suffer from bothersome symptoms of OAB, which can have a significant impairment on a patient's day-to-day activities.<sup>3,4</sup>

### What is 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.

#### **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 approved by the U.S. FDA in December 2020 for the treatment of adult patients with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency. GEMTESA is also being evaluated for the treatment of OAB in men with benign prostatic hyperplasia (OAB+BPH). 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 subsidiary of Sumitomo Dainippon Pharma Co., Ltd., intends to develop novel treatments for additional urologic diseases. Learn more about us at [www.urovant.com](http://www.urovant.com).

#### **About Sumitovant Biopharma Ltd.**

Sumitovant is a global biopharmaceutical company with offices in New York City and London. Sumitovant is a wholly owned subsidiary of Sumitomo Dainippon Pharma. Sumitovant is the majority shareholder of Myovant Sciences and Urovant Sciences, and wholly owns Enzyvant Therapeutics, Spirovant Sciences, and Altavant Sciences. Sumitovant's promising pipeline is comprised of early-through late-stage investigational medicines across a range of disease areas targeting high unmet need. For further information about Sumitovant, please visit <https://www.sumitovant.com>.

#### **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 the European Union. 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 6,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at <https://www.ds-pharma.com>.

#### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical statements of fact and statements regarding the Company's intent, belief or expectations and can be identified by words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "strive," "to be," "will," "would," or the negative or plural of these words or other similar expressions or variations, although not all forward-looking statements contain these identifying words. In this press release, forward-looking statements include, but are not limited to, statements regarding the impact of vibegron on patients' OAB symptoms and Urovant's expectations regarding the planned commercial launch and footprint for vibegron. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to, risks associated with: the success and cost of Urovant's efforts to commercialize vibegron; Urovant's ability to realize the anticipated benefits of the co-promotion agreement with Sunovion in the manner or timeline expected; Urovant's reliance on Sunovion for the co-promotion and distribution of vibegron and Urovant's ability to secure alternative access to commercial infrastructure or strategic collaborations for the commercialization or distribution of products if it is unable to continue the relationship with Sunovion; the success, cost, and timing of Urovant's development activities, including the timing of the initiation and completion of clinical trials and the timing of expected regulatory filings; the clinical utility and potential attributes and benefits of vibegron, including reliance on collaboration partners and the ability to procure additional sources of financing; our intellectual property position, including the ability to identify and in-license or acquire third-party patents and licenses, and associated costs; and other risks and uncertainties listed in the Company's filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's most recently filed Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q filed with the SEC, as such risk factors may be amended, supplemented or superseded from time to time by other filings with the SEC. Given these risks and uncertainties, you should not place undue reliance on any forward-looking statements. These forward-looking statements are based on information available to Urovant as of the date of this press release and speak only as of the date of this release. Urovant disclaims any obligation to update these forward-looking statements, except as may be required by law.

1. Staskin, D., 2020. International Phase III, Randomized, Double-Blind, Placebo and Active Controlled Study to Evaluate the Safety and Efficacy of Vibegron in Patients with Symptoms of Overactive Bladder: EMPOWUR | Journal of Urology. <https://www.auajournals.org/doi/10.1097/JU.0000000000000807>
2. 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>
3. 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. <https://doi.org/10.1016/j.urology.2010.08.039>
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