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

Nationwide availability gives healthcare providers and patients a new treatment option

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IRVINE, Calif. & BASEL, Switzerland–(BUSINESS WIRE) – Urovant Sciences, a biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions, today announced the commercial launch of GEMTESA® (vibegron) 75 mg tablets, a beta-3 (β3) adrenergic receptor agonist, for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence (UUI), urgency, and urinary frequency in adults.

“Urovant is excited to introduce GEMTESA to the patients and healthcare providers who are in need of a new treatment option to address the bothersome symptoms of OAB,” said Jim Robinson, president and chief executive officer of Urovant. “The launch of GEMTESA is a significant milestone for Urovant, as we are bringing our first product to market. It is also an important moment for the entire urology community, as GEMTESA is the first new, oral branded OAB medication to reach the market in nearly a decade.”

Adults suffering from OAB may experience symptoms of UUI, urgency and urinary frequency, which can have a significant impact on daily activities. GEMTESA is designed to reduce the bothersome symptoms of OAB by relaxing the detrusor bladder muscle so that the bladder can hold more urine. GEMTESA was approved by the U.S. Food and Drug Administration in December 2020 and is the first and only β3 agonist with urgency data and no blood pressure warning in its label. In clinical studies, GEMTESA has been shown to significantly reduce all three key OAB symptoms compared to placebo at Week 12, and there is no known association with cognitive decline for the beta-3 agonist class.1

“The availability of GEMTESA is an important step forward in providing patients with a safe, effective option to manage their OAB symptoms,” said Scott A. MacDiarmid, M.D., FRCPSC, Urologist, Alliance Urology Specialists. “GEMTESA will enable us to deliver a patient-centric treatment experience, bringing a new beta-3 agonist to the forefront of the OAB treatment landscape.”

“Many patients continue to suffer from the symptoms of OAB,” said Walt Johnston, executive vice president, commercial, Urovant. “Our robust teams are working diligently to bring GEMTESA to urology specialists, those in a long-term care setting, and other healthcare providers. We look forward to making GEMTESA available nationwide, supported by comprehensive physician and patient education.”

To learn more about GEMTESA, please visit 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).2

Approximately 30 million Americans suffer from bothersome symptoms of OAB, which can have a significant impairment on a patient’s day-to-day activities.2,3

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 is a wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. and intends to develop novel treatments for additional urologic diseases. Learn more about us at 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 wholly owns Urovant Sciences, 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.

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