Urovant Sciences and Sunovion Pharmaceuticals Launch Primary Care Co-Promotion of GEMTESA® (vibegron) for Patients with Overactive Bladder

•Co-promotion extends sales and market access efforts to reach primary care physicians who treat OAB patients

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IRVINE, Calif. & BASEL, Switzerland & MARLBOROUGH, Mass., June 29, 2021 at 9:00 AM EDT (BUSINESS WIRE)– Urovant Sciences, Inc. and Sunovion Pharmaceuticals Inc. today announced the launch of co-promotion activities for GEMTESA® (vibegron) 75 mg tablets to extend promotion to primary care physicians through the deployment of Sunovion's multi-specialty sales force. The collaboration is covered by a five-year U.S. co-promotion agreement between the two companies reached in October 2020.

The commercial launch of GEMTESA, a beta-3 (β3) adrenergic receptor agonist, was announced in April 2021. In December 2020, the therapy received U.S. Food and Drug Administration approval for the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence (UUI), urgency, and urinary frequency.

Urovant and Sunovion also have in place an exclusive three-year agreement signed in June 2020 for services related to wholesale trade and retail distribution, contract operations, and select account management activities for GEMTESA. Both Urovant and Sunovion are indirect, wholly owned subsidiaries of Sumitomo Dainippon Pharma Co., Ltd.

"Initiating this co-promotion agreement will accelerate the launch of GEMTESA to the U.S. primary care community," said Walt Johnston, executive vice president, commercial, at Urovant. "Primary care physicians play a key role in identifying and treating patients with OAB. This collaboration between Urovant and Sunovion highlights the strategic benefit of our affiliation with the Sumitomo Dainippon Pharma Group of companies."

"The co-promotion efforts will leverage Sunovion's extensive primary care commercial capabilities and expertise," said Thomas Gibbs, senior vice president and chief commercial officer of Sunovion. "In partnership with Urovant, we aim to bring this treatment option to more of the estimated 30 million Americans who suffer from symptoms of OAB."

GEMTESA reduces 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]

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]

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 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 Sumitovant Biopharma Ltd., intends to develop novel treatments for additional urologic diseases. Learn more about us at www.urovant.com.

About Sunovion Pharmaceuticals
Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion's vision is to lead the way to a healthier world. The company's spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. With patients at the center of everything it does, Sunovion has charted new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to support people with psychiatric, neurological and respiratory conditions. Headquartered in Marlborough, Mass., Sunovion is an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. Sunovion Pharmaceuticals Europe Ltd., based in London, England, and Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's websites: www.sunovion.com, www.sunovion.eu and www.sunovion.ca. Connect with Sunovion on Twitter, LinkedIn, Facebook and YouTube.

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-10 listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China, and the European Union. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area, the Oncology area and Regenerative medicine/Cell therapy field, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 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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