



Urovant Sciences to Present New Ambulatory Blood Pressure Data in Patients Dosed With GEMTESA® (vibegron) 75 mg for Overactive Bladder at the 2021 Annual Meeting of the American Urological Association

August 18, 2021

- *Data from the dedicated, stand-alone, ambulatory blood pressure trial will be the focus of a podium presentation*
- *Efficacy in patients with 'dry' overactive bladder, based on a post-hoc analysis of the pivotal EMPOWUR trial, will be the topic of a poster presentation*

IRVINE, Calif. and BASEL, Switzerland – (BUSINESS WIRE) – Urovant Sciences, Inc., a wholly-owned subsidiary of Sumitovant Biopharma Ltd., today announced key data for GEMTESA® (vibegron) 75 mg to be presented at the 2021 Annual Meeting of the American Urological Association (AUA2021). GEMTESA was approved by the U.S. Food and Drug Administration for the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence (UUI), urgency, and urinary frequency.

The AUA21 podium presentation will examine new clinical trial data on the effect of GEMTESA on ambulatory blood pressure in OAB patients. A separate poster presentation will demonstrate its efficacy in patients with 'dry' overactive bladder (without urinary leakage), based on a post-hoc analysis of data from the pivotal EMPOWUR study. The conference will be held in person in Las Vegas, NV, and virtually, on September 10-13.

"We are eager to share new data and analyses that support the unique safety and efficacy profile of GEMTESA in overactive bladder," said Cornelia Haag-Molkenteller, MD, PhD, EVP and Chief Medical Officer at Urovant. "We believe that GEMTESA can help meet the needs of the estimated 30 million Americans who suffer from the bothersome symptoms of this condition. We also look forward to robust scientific exchanges at the conference."

Data on GEMTESA will be featured in two presentations at the conference:

1. [Abstract #PD66-11](#) by Michael A. Weber, MD, professor of medicine at Downstate College of Medicine of the State University of New York, Brooklyn, NY, titled, "*Effects of Vibegron on Ambulatory Blood Pressure in Patients with Overactive Bladder: Results from a Double-Blind Study.*" This podium presentation will take place on Monday, September 13, during a session from 1:00 to 3:00 p.m. PDT at the Venetian-Sands Expo Center, Marco Polo room 701.
2. [Abstract #MP63-15](#) by David Staskin, MD, associate professor of urology, Tufts University School of Medicine, and director, Center for Male and Female Pelvic Health, St. Elizabeth's Medical Center, Boston, titled, "*Vibegron for the Treatment of Patients with Dry Overactive Bladder: A Subgroup Analysis from the EMPOWUR Trial.*" This poster presentation will take place on Monday, September 13, between 10:30 and 11:45 a.m. PDT in the Venetian-Sands Expo Center, Casanova room 501.

Abstracts are available on the [Journal of Urology website](#) and will be published in the journal on September 1.

In addition, Urovant has provided an unrestricted educational grant to support

- A CME Symposium will be held on Sunday, September 12, from 4:30 to 6:30 p.m. PDT "New Treatment Strategies and Considerations in OAB to Improve Patient Outcomes" (Venetian Resort Ballroom: Venetian E-L). The symposium will be chaired by Roger Dmochowski, MD, MMHC, FACS; with Benjamin M. Brucker, MD and Alan J Wein, MD, PhD (Hon), FACS as faculty.

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 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 subsidiary of Sumitovant Biopharma Ltd., 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 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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