Urovant Sciences Announces Publication of Positive Long-Term Clinical Safety and Efficacy Data on the FDA-Approved Overactive Bladder Therapy, GEMTESA® (vibegron), in the Journal of Urology

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EMPOWUR extension study demonstrates favorable results in long-term treatment of overactive bladder with GEMTESA, including favorable tolerability and improvements in incontinence efficacy endpoints

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Urovant Sciences, a wholly owned subsidiary of Sumitovant, announced today that the *Journal of Urology* has published positive safety and efficacy data from the GEMTESA® (vibegron) double-blind 40-week extension study with patient data over a total exposure of 52 weeks (NCT03583372) in the print version of the *Journal of Urology*. The peer-reviewed publication is currently available online and the print article is scheduled to be published in the May issue of the journal.

The published analysis supports the safety and efficacy of GEMTESA for the treatment of overactive bladder (OAB) in patients with symptoms of urge urinary incontinence (UUI), urgency, and urinary frequency.

GEMTESA, a once-daily, beta-3 adrenergic agonist, received U.S. Food and Drug Administration approval in December 2020 for the treatment of OAB. Over the total exposure of 52 weeks, starting with the 12-week placebo-controlled phase 3 EMPOWUR study and continuing with the 40-week extension study, 75 mg of GEMTESA continued to demonstrate efficacy and be well tolerated. These data were presented at the virtual American Urological Association (AUA) Annual Meeting in 2020, and are consistent with the results from the EMPOWUR study, where patients receiving treatment with 75 mg GEMTESA experienced reductions in daily micturitions (urination), UUI, urgency, and total urinary incontinence episodes over the 12-week period. GEMTESA also demonstrated a favorable safety profile over 12 weeks.

Dr. David Staskin, the principal EMPOWUR study investigator and lead author of the *Journal of Urology* paper, said, “This peer-reviewed journal publication further highlights the results of the EMPOWUR study over the 52-week period, demonstrating the favorable long-term safety, tolerability and efficacy of GEMTESA in patients with overactive bladder, consistent with results of the 12-week EMPOWUR study. This is a potentially important and differentiated new oral treatment for patients suffering with OAB.” Dr. Staskin is a leading urologist with St. Elizabeth’s Medical Center, and an Associate Professor of Urology at Tufts University School of Medicine in Boston.

A total of 12 patients (2.4%) discontinued owing to adverse events. The most common adverse events with vibegron/tolterodine (active control) that were seen in >5% of patients in either group were hypertension (8.8%/8.6%), urinary tract infection (6.6%/7.3%), headache (5.5%/3.9%), nasopharyngitis (4.8%/5.2%) and dry mouth (1.8%/5.2%).

About the EMPOWUR Trial

The EMPOWUR trial was an international, randomized, double-blind, placebo and active comparator-controlled phase 3 clinical trial evaluating the safety and efficacy of investigational vibegron in men and women with symptoms of overactive bladder, including frequent urination, sudden urge to urinate, and urge incontinence or leakage. A total of 1,518 patients were randomized across 215 study sites into one of three groups for a 12-week treatment period with a four-week safety follow-up period: vibegron 75 mg administered orally once daily; placebo administered orally once daily; or tolterodine ER 4 mg administered orally once daily.

About the 40-Week EMPOWUR Extension

The EMPOWUR 40-week extension trial was a phase 3, randomized, double blind, active controlled multicenter study to evaluate the long-term safety and efficacy of vibegron in patients with symptoms of overactive bladder. The extension study enrolled approximately 500 EMPOWUR completers. The primary endpoint was safety, measured by incidence of adverse events. Secondary endpoints were changes from EMPOWUR baseline at week 52 in average daily micturitions, UUI, urgency, and total urinary incontinence.

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 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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