Urovant Sciences Presents Positive Clinical Efficacy & Safety Data on Lead Drug Candidate Vibegron at Virtual American Urological Association Annual Meeting

May 14, 2020

52-Week Post Hoc Analysis Shows Vibegron Patients Had Statistically Significant, Sustained Reduction in UUI and Total Incontinence Episodes Compared to Active Control

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--May 14, 2020-- Urovant Sciences (Nasdaq: UROV) announced today that data from the vibegron EMPOWUR 52-week extension study (NCT03583372) and data by age groups from the 12-week placebo-controlled EMPOWUR study (NCT03492281) will be presented virtually by the authors during the 2020 American Urological Association (AUA) Annual Meeting and will be available for viewing on the annual meeting website, on May 15, 2020.

The data sets that will be presented support the potential benefits of vibegron for the treatment of overactive bladder (OAB) in patients with symptoms of urge urinary incontinence (UUI), urgency, and urinary frequency, if approved by the U.S. Food and Drug Administration (FDA).

Vibegron is a once-daily, beta-3 adrenergic agonist under investigation for the treatment of OAB. Twelve-week data from the EMPOWUR study were previously presented at the annual AUA meeting in 2019. These data demonstrated statistically significant improvements in the co-primary OAB endpoints of daily urination (micturitions) and UUI, and key secondary endpoints, including urgency episodes, in patients treated with vibegron 75 mg vs placebo. The data also demonstrated a favorable safety and tolerability profile.

The first Urovant presentation focuses on the 52-week results from the double-blind vibegron 75 mg EMPOWUR extension study. In this study, patients receiving treatment with 75 mg vibegron experienced sustained reductions in daily micturitions, UUI, urgency, and total urinary incontinence episodes over the 52-week period. Vibegron also demonstrated a favorable long-term safety profile over the 52 weeks. In addition, in a *post hoc* analysis, vibegron showed a statistically significant reduction in UUI and total incontinence episodes, from baseline to 52 weeks, compared to the active control, tolterodine.

Dr. David Staskin, the principal EMPOWUR study investigator, a leading urologist with St. Elizabeth's Medical Center, and an Associate Professor of Urology at Tufts University School of Medicine in Boston, will narrate this presentation.

"The results of the EMPOWUR study over the 52-week period demonstrated the sustained benefits of vibegron. Vibegron could be a potentially important and differentiated new oral treatment, if approved by the FDA, for patients suffering with OAB," said Dr. Staskin.

The second Urovant presentation examines data from the international, double-blind vibegron 75 mg 12-week EMPOWUR study by age, with a focus on older patients. For patients aged 65 years and older, statistically significant improvements were seen with 75 mg vibegron compared with placebo in the co-primary endpoints of micturitions and UUI episodes, as well as key secondary endpoints, including urgency episodes. Overall, adverse event rates were comparable between older patients and the total study population.

Dr. Jeffrey Frankel, a key EMPOWUR study investigator and Medical Director of Seattle Urology Research Center in Burien, Washington, will narrate this presentation.

"The EMPOWUR 12-week study efficacy and safety results in patients age 65 and older are encouraging, and important because the prevalence of OAB increases with age," said Dr. Frankel. "Many of these patients are taking multiple drugs and the favorable drug-drug interaction profile and overall efficacy, safety, and tolerability profile will be an important aspect of vibegron if approved."

Both presentations can be accessed on the annual meeting website on May 15.

Virtual Presentation Details:

Session Title: Urodynamics/Lower Urinary Tract Dysfunction/Female Pelvic Medicine: Non-Neurogenic Voiding Dysfunction I

Reference: PD21

Abstract Number 01: Once-Daily Vibegron 75 mg for Overactive Bladder (OAB): Double-Blind 52-Week Results from an Extension Study of the International Phase 3 Trial (EMPOWUR). The abstract is available to view here.

Abstract Number 02: Efficacy of once-Daily Vibegron 75 mg for Overactive Bladder (OAB) in Older Patients: The EMPOWUR Randomized, International, Phase 3 Study. The abstract is available to view here.

About the Phase 3 Trial

The EMPOWUR trial was an international, randomized, double-blind, placebo and active comparator-controlled 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 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. Key efficacy 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 clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. The Company's lead product candidate, vibegron, is an oral, once-daily small molecule beta-3 agonist that is being evaluated for overactive bladder (OAB). Urovant Sciences reported positive data from the vibegron 12-week, Phase 3 pivotal EMPOWUR study and demonstrated favorable longer-term efficacy, safety, and tolerability in a 40-week extension study. The Company submitted a New Drug Application to the FDA seeking approval of vibegron for the treatment of patients with OAB in December 2019. Vibegron is also being evaluated for treatment of OAB in men with benign prostatic hyperplasia (OAB+BPH) and for abdominal pain associated with irritable bowel syndrome (IBS). Urovant'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., which is a wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., 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 and Urovant, and wholly owns Enzyvant, Spirovant, and Altavant. 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 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.

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 Urovant's plans to advance the clinical development and seek U.S. FDA approval of vibegron in patients with OAB. 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, 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.

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