Urovant Sciences Announces Publication of Phase 3 EMPOWUR Trial Results in the Journal of Urology

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IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)-- Urovant Sciences (Nasdaq: UROV) announced today the publication of the efficacy and safety results of vibegron in patients with overactive bladder (OAB) from the international Phase 3 EMPOWUR trial. The peer-reviewed publication is currently available online and the print article is scheduled to be published in the August issue of *Journal of Urology*.

The double-blind, placebo-controlled 12-week trial, in patients with OAB, studied vibegron 75 mg once-daily compared to placebo and included an active control. In the trial, vibegron achieved rapid onset of action at two weeks in both co-primary endpoints and daily urgency episodes and statistically significant efficacy was maintained at all timepoints measured through the end of the study. Vibegron also achieved statistical significance over placebo on all 7 key secondary endpoints, including the most important secondary endpoint of reduction in urgency episodes. Vibegron demonstrated consistent efficacy, a favorable safety profile, and was well tolerated. The frequency of serious adverse events was similar across treatment arms and the incidence of the reported adverse event of hypertension for vibegron was equal to placebo. The New Drug Application (NDA) seeking approval of once-daily 75 mg vibegron for the treatment of patients with overactive bladder (OAB) was submitted to the U.S. Food and Drug Administration (FDA) in December 2019.

“Over 30 million people in the U.S. suffer from OAB symptoms and many patients are unable to find relief,” said Dr. David Staskin, a key investigator in the EMPOWUR study, a leading urologist with St. Elizabeth’s Medical Center, and an Associate Professor of Urology at Tufts University School of Medicine in Boston. “The results of this clinical trial have demonstrated that vibegron, if approved by the FDA, could provide an important new oral treatment for patients suffering with OAB.”

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.

The full publication can be accessed online **here**.

About Vibegron

Vibegron is a once-daily, beta-3 adrenergic agonist under investigation for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

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 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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Investor inquiries:
Ryan Kubota
949.769.2706
ryan.kubota@urovant.com

Media inquiries:
media@urovant.com

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