Urovant Sciences Reports Positive Long-Term Data from the Double-Blind Extension of the Phase 3 EMPOWUR Study of Vibegron in Patients with Overactive Bladder

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- *Vibegron further improved treatment benefit on key overactive bladder (OAB) symptoms over the 40-week extension period*
- *41% of patients on vibegron became "dry," defined as having no urge urinary incontinence episodes at week 52*
- *Vibegron demonstrated a favorable long-term safety and tolerability profile consistent with previous clinical experience*
- *Over 2,600 OAB patients have been treated with vibegron in clinical trials*
- *New Drug Application for vibegron expected to be submitted by early 2020*

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Sep. 24, 2019--

Urovant Sciences (Nasdaq: UROV), a clinical-stage biopharmaceutical company focused on developing novel therapies for urologic conditions, today announced positive data from the ongoing double-blind extension of the Phase 3 trial of its investigational drug candidate vibegron, a next-generation, once-daily oral beta-three adrenergic agonist in development for the treatment of overactive bladder.

As previously reported, once-daily vibegron met both co-primary endpoints in the 12-week Phase 3 EMPOWUR study, achieving statistical significance over placebo on both reduction in daily urge urinary incontinence (UUI) episodes ($p<0.0001$) and reduction in daily micturitions ($p<0.001$).

Highlights from the double-blind extension of the Phase 3 EMPOWUR study include:

- Vibegron further improved treatment benefit on key OAB symptoms (micturitions, UUI, urgency, and total incontinence) over the 40-week extension period
- 61% of patients on vibegron achieved at least a 75% reduction in their daily urge urinary incontinence episodes from baseline at week 52
- 41% of patients on vibegron became "dry," defined as having no urge urinary incontinence episodes at week 52
- Vibegron demonstrated a favorable long-term safety and tolerability profile consistent with previous clinical experience

"The double-blind extension of the EMPOWUR study provides further compelling data that vibegron has the potential to provide long-term benefits for people suffering with overactive bladder," said Dr. Cornelia Haag-Molkenteller, Chief Medical Officer at Urovant. "These data increase our confidence in the vibegron OAB development program and we believe vibegron has the potential, if approved by the FDA, to become an exciting next-generation treatment option for patients suffering from OAB."

More details from the extension study will be presented at future medical meetings. Urovant intends to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) by early 2020.

About EMPOWUR

EMPOWUR 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. Additionally, 506 patients who completed the EMPOWUR trial were enrolled in a 40-week double-blind extension study

to evaluate the safety of longer-term treatment up to 52 weeks. The co-primary endpoints of the EMPOWUR study were: change from baseline in the average number of micturitions per 24 hours; and change from baseline in the average number of urge urinary incontinence (UUI) episodes per 24 hours in patients who have an average of one or more UUI episodes per day prior to treatment. Secondary endpoints included changes in the frequency of urinary urgency episodes and incontinence episodes, and self-reported quality of life scores.

About Urovant Sciences

Urovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Urovant's lead product candidate, vibegron, is an oral, once-daily, small molecule beta-3 agonist being evaluated for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency. Urovant has licensed global rights, excluding Japan and certain Asian territories, for the development and commercialization of vibegron. Urovant's second product candidate, URO-902, is a novel gene therapy being developed for patients with OAB who have failed oral pharmacological therapy. Urovant intends to develop treatments for additional urologic diseases. For more information, please visit www.urovant.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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