Urovant Sciences Announces Positive Topline Results from Pivotal Phase 3 EMPOWUR Study of Vibegron in Patients with Overactive Bladder

March 19, 2019

- *Vibegron met both co-primary endpoints demonstrating highly significant reduction in daily urge urinary incontinence episodes and micturitions, compared to placebo (p<0.0001 and p<0.001, respectively)*
- *Vibegron met all seven key secondary endpoints, including a clinically meaningful reduction in daily urgency episodes versus placebo (p=0.002)*
- *Vibegron achieved rapid onset at two weeks in both co-primary endpoints and daily urgency episodes (p<0.001 for these endpoints) and statistically significant efficacy was maintained at all timepoints measured through the end of the study*
- *Vibegron could potentially be the first new prescription drug in nearly a decade for the millions of patients suffering from overactive bladder (OAB)*
- *Urovant to host investor conference call March 19, 2019*

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Mar. 19, 2019-- Urovant Sciences (Nasdaq: UROV),a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions, today announced positive topline results from EMPOWUR, an international double-blind, placebo-controlled, multicenter Phase 3 clinical trial evaluating the efficacy and safety of vibegron 75mg in adults with symptoms of overactive bladder. Vibegron is an investigational once-daily oral beta-three adrenergic agonist.

In the primary efficacy analysis, once-daily vibegron met the co-primary endpoints at week 12, 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). The difference from placebo was statistically significant as early as week 2, which was the first timepoint measured, for both UUI episodes and micturitions (p<0.0001 and p<0.001, respectively), and statistically significant efficacy was maintained at all timepoints measured through the end of the study for both endpoints. Additionally, at all measured timepoints, vibegron achieved numerically better efficacy than tolterodine, the active control in this study, which is a currently available OAB treatment.

All seven pre-specified key secondary endpoints were met, including a statistically significant reduction in daily urgency episodes compared to placebo (p=0.002). Other endpoints that were not part of the topline data analysis will be presented at future medical meetings.

Vibegron was well tolerated and the most common adverse events reported versus placebo (>2% in vibegron and greater than placebo) were headache (4.0% vs 2.4%), nasopharyngitis (2.8% vs 1.7%), diarrhea (2.2% vs 1.1%), and nausea (2.2% vs 1.1%). The frequency of serious adverse events was similar across treatment arms (1.1% in placebo, 1.5% in vibegron, and 2.3% in tolterodine). The incidence of the reported adverse event of hypertension was equal to placebo (1.7% in vibegron, 1.7% in placebo, and 2.6% in tolterodine). Full vital sign data, including blood pressure, were not part of the topline data analysis.

Based on these topline results, Urovant intends to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) by early 2020. EMPOWUR results will be presented at the American Urological Association Annual Meeting in Chicago in May of this year.

“There is a significant need for innovative new treatment options for OAB patients, as many patients are unable to find relief with currently available medicines,” said Dr. David R. 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 strong efficacy and safety topline results from the EMPOWUR study suggest that vibegron, if approved by the FDA, could provide an exciting next-generation treatment option for patients suffering from OAB.”

“We believe these efficacy and safety results represent a significant advancement in the treatment of OAB, positioning vibegron as a potential best in class therapy,” said Keith A. Katkin, Chief Executive Officer of Urovant. “Vibegron, if approved, could potentially be the first new prescription drug in nearly a decade for the millions of women and men suffering from OAB.”

About EMPOWUR

EMPOWUR is 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, 507 patients who completed the EMPOWUR trial were enrolled in a 40-week double-blind extension study to evaluate the safety of longer-term treatment. The co-primary endpoints of the EMPOWUR study are: 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.

Conference Call

Urovant will host a conference call today March 19, 2019 at 8:30 a.m. ET to discuss topline results from EMPOWUR, the international Phase 3 pivotal trial for vibegron. The conference call numbers are (866) 470-1049 for domestic callers and +1 (409) 217-8245 for international callers. The conference ID is 9455883. The webcast link to view the presentation is available at: https://edge.media-server.com/m6/p/oey7muvz.

A replay of the call will be available approximately four hours after the call and accessible for 30 days at (855) 859-2056 for domestic callers and +1 (404)-537-3406. The conference ID is 9455883. A webcast will be archived on the Investor Relations page of the Urovant Sciences website immediately after the call and available for at least 30 days.

About Overactive Bladder

Overactive bladder is a clinical condition characterized by the sudden urge to urinate that is difficult to control (urgency), with or without accidental urinary leakage (urge urinary incontinence), and usually with increased frequency of urination. The exact cause is unknown, making this a difficult condition to treat. In the United States, more than 30 million people over the age of 40 suffer from the bothersome symptoms of OAB[1], which can lead to depression, anxiety and a negative impact on quality of life.[2]

About Urovant Sciences

Urovant Sciences, a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions, is a subsidiary of Roivant Sciences. Urovant leverages the Roivant platform to develop therapies that address high unmet medical needs while driving greater efficiency in research, clinical development, and commercialization. Urovant's lead product candidate, vibegron, is an oral, once-daily, small molecule beta-3 adrenergic agonist being evaluated for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency; for OAB in men with benign prostatic hyperplasia; and for abdominal pain associated with irritable bowel syndrome. 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.

About Roivant Sciences

Roivant aims to improve health by rapidly delivering innovative medicines and technologies to patients. Roivant does this by building Vants – nimble, entrepreneurial biotech and healthcare technology companies with a unique approach to sourcing talent, aligning incentives, and deploying technology to drive greater efficiency in R&D and commercialization. For more information, please visit www.roivant.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," "suggest," "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 the Company's plans and strategies for the development and commercialization of innovative therapies for the treatment of urological conditions, the Company's plans to file for approval of vibegron with the FDA, and the timing of such filing and the likelihood of FDA approval.

The Company's forward-looking statements are based on management's current expectations and beliefs, and are subject to a number of risks and uncertainties that could lead to actual results differing materially from those projected, forecasted or expected. Although the Company believes that the assumptions underlying these forward-looking statements are reasonable, they are not guarantees and the Company can give no assurance that its expectations will be attained. Factors that could materially affect the Company's operations and future prospects or which could cause actual results to differ materially from expectations include, but are not limited to the 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 Quarterly Report on Form 10-Q filed with the SEC on February 14, 2019, as such risk factors may be amended, supplemented or superseded from time to time by other reports the Company files with the SEC. You should not place undue reliance on the forward-looking statements in this press release, which speak only as of the date hereof, and, except as required by law, the Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

1. Coyne, et al., EpiLUTS 2007
2. Kinsey D, et al., J Health Psychol. 2016

View source version on businesswire.com: https://www.businesswire.com/news/home/20190319005314/en/

Source: Urovant Sciences

Investor inquiries: Investors@Urovant.com
Media inquiries: Media@Urovant.com