Urovant Sciences Presents Positive Pivotal Data for Vibegron During Plenary Session at American Urological Association Annual Meeting

May 6, 2019

- *Pivotal Phase 3 EMPOWUR study met both co-primary endpoints, with significant reduction in daily urge urinary incontinence episodes and micturitions, compared to placebo ($p<0.0001$ and $p<0.001$, respectively), and a favorable safety and tolerability profile*
- *Efficacy observed at week 2 and maintained through week 12 in co-primary endpoints*
- *Data showed once-daily 75 mg dose has potential to be an efficacious agent for disruptive overactive bladder symptoms for broad base of patients*

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--May 6, 2019-- Urovant Sciences (Nasdaq: UROV),a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions, today announced Dr. David Staskin presented positive, Phase 3 pivotal data demonstrating safety and efficacy of vibegron during a plenary session at the 2019 American Urological Association Annual Meeting (AUA) in Chicago yesterday afternoon. Vibegron is an investigational novel, once-daily oral beta-3 adrenergic agonist being evaluated as a treatment for adults with symptoms of overactive bladder (OAB). Dr. Staskin, a leading urologist with St. Elizabeth's Medical Center, and an Associate Professor of Urology at Tufts University School of Medicine in Boston, is a key investigator for vibegron.

Data from EMPOWUR – an international double blind, placebo-controlled, multicenter Phase 3 clinical trial evaluating the efficacy and safety of a once-daily 75 mg dose of vibegron – showed statistical significance over placebo in both reduction in daily urge urinary incontinence (UUI) episodes ($p<0.001$) and reduction in daily micturitions ($p<0.001$). The difference compared to placebo was statistically significant as early as week 2 for UUI and micturitions ($p<0.001$ and $p<0.001$, respectively) and statistically significant efficacy was maintained at all timepoints measured through the end of the study. In addition, vibegron met all seven key secondary endpoints, including a clinically meaningful reduction in daily urgency episodes and volume voided versus placebo.

A patient subset-analysis of the data were also included in the plenary presentation at AUA, showing vibegron reduced UUI and micturitions in patients previously treated for OAB symptoms with an anticholinergic or mirabegron, the only currently marketed beta-3 agonist.

"There is a need for a new treatment option with rapid onset in a once-daily, convenient dose for patients suffering from OAB symptoms," said Dr. Staskin. "The EMPOWUR data suggests that vibegron, if approved, could be suitable for a large base of patients."

Urovant intends to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) by early 2020.

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 and efficacy 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.

About Overactive Bladder

Overactive bladder (OAB) 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 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; 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.

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 the Company's plans and strategies for the development and commercialization of innovative therapies, including vibegron, for the treatment of urological conditions.

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/20190506005206/en/

Source: Urovant Sciences

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