Urovant Sciences Initiates Phase 3 Clinical Program for Vibegron in Patients with Overactive Bladder

March 28, 2018

- Pivotal trial will enroll approximately 1,400 patients for 12-week treatment period
- Program supported by prior dosing in 2,350 subjects and positive Phase 2b and Phase 3 results

BASEL, Switzerland and IRVINE, Calif., March 28, 2018 /PRNewswire/ — Urovant Sciences, a global biopharmaceutical company focused on developing novel therapies for urologic conditions, today announced that it has initiated an international Phase 3 trial, EMPOWUR, to evaluate the safety and efficacy of vibegron, an investigational oral β3-adrenergic agonist, in adults with symptoms of overactive bladder.

"I am proud of our team's efforts to rapidly launch this pivotal study for a promising therapy," said Keith Katkin, Chief Executive Officer of Urovant. "Overactive bladder affects millions of individuals and patients need better alternatives to the current standard of care."

Vibegron has been previously evaluated in 16 Phase 1 studies, one large international Phase 2b dose-ranging study in patients with overactive bladder, and a successful Phase 3 program in Japanese patients with overactive bladder.

About the Phase 3 Trial

The EMPOWUR study is a randomized, double-blind, placebo- and active comparator-controlled international Phase 3 clinical trial in men and women with symptoms of overactive bladder. The study is expected to enroll approximately 1,400 patients.

Individuals who meet eligibility requirements will be randomized to one of three groups for a 12-week treatment period: vibegron 75 mg administered orally once daily, placebo administered orally once daily, or tolterodine ER 4 mg administered orally once daily. Eligible patients completing the initial 12-week blinded assessment will be offered the opportunity to enroll in a 40-week double-blind extension study to evaluate the safety of longer-term treatment.

The co-primary efficacy endpoints of the study are:

- Change from baseline in the average number of micturitions per 24 hours in all patients
- Change from baseline in the average number of urge urinary incontinence (UUI) episodes per 24 hours in patients with an average of ≥ 1 UUI episodes per day prior to treatment

Secondary endpoints will include changes in the frequency of incontinence episodes and urinary urgency episodes, and self-reported quality of life scores. Adverse events will be monitored during both the trial and the extension study.

About Overactive Bladder

Overactive bladder (OAB) is a condition that affects as many as 46 million adults in the United States alone. The most common symptoms of OAB include the experience of sudden urges to urinate that cannot be controlled, frequent urination, and urinary incontinence due to involuntary contractions of the detrusor muscle. While several conditions may contribute to signs and symptoms of overactive bladder, the underlying cause of OAB remains unclear.

About Vibegron

Vibegron is an investigational oral β3-adrenergic agonist being studied for the treatment of OAB. β3-adrenergic receptors play a role in the bladder fill-void cycle. By stimulating that pathway, vibegron has the potential to relax the bladder detrusor muscle. Relaxing the bladder allows it to store urine more efficiently, thereby decreasing the symptoms of OAB. Over 2,700 patients with symptoms of OAB have previously been enrolled in clinical studies evaluating the safety and efficacy of vibegron and over 2,350 individuals have received vibegron in past studies.

About Urovant Sciences

Urovant Sciences is a global biopharmaceutical company focused on developing novel therapies for urologic conditions. Urovant's lead therapeutic candidate is vibegron, a selective β3-adrenergic agonist being developed for the treatment of overactive bladder 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 intends to develop treatments for additional urologic diseases. For more information, please visit urovant.com.