Urovant Sciences Logo

Urovant Sciences Completes Patient Enrollment in Phase 3 Pivotal Trial Studying Vibegron for Overactive Bladder

November 8, 2018

- *More than 1,500 patients enrolled in international Phase 3 clinical trial EMPOWUR, exceeding recruitment target*
- *Top-line efficacy and safety data from Phase 3 trial expected by the end of March 2019*

BASEL, Switzerland & IRVINE, Calif.--(BUSINESS WIRE)--Nov. 8, 2018-- Urovant Sciences (Nasdaq: UROV), a clinical-stage biopharmaceutical company focused on developing novel therapies for urologic conditions, today announced it completed enrollment in its international Phase 3 clinical trial, EMPOWUR, evaluating the safety and efficacy of vibegron as a treatment for adults with symptoms of overactive bladder. Vibegron is an investigational oral beta-3 adrenergic agonist.

“I am proud of the progress made since initiating our robust EMPOWUR clinical trial in March of 2018,” said Dr. Cornelia Haag-Molkenteller, Chief Medical Officer of Urovant. “Exceeding our enrollment ahead of schedule underscores the interest in this trial and reinforces the need for this significantly underserved patient population.”

EMPOWUR is a randomized, double-blind placebo- and active comparator controlled clinical trial in men and women with symptoms of overactive bladder, including frequent urination, sudden urge to urinate, and urge incontinence or leakage. Top-line efficacy and safety data are anticipated by the end of March 2019.

A total of 1,530 patients who met the enrollment criteria were randomized across 216 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, the first 507 patients who completed the EMPOWUR trial have been 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 in all patients
- Change from baseline in the average number of urge urinary incontinence (UUI) episodes per 24 hours in patients who have one or more UUI episodes per day prior to treatment

Vibegron, which has been widely studied and recently received regulatory approval in Japan, is investigational in the United States and has not been approved by the U.S. Food and Drug Administration. Vibegron has previously been evaluated in multiple clinical trials with more than 2,600 OAB patients, including a completed international randomized, double-blind, placebo-controlled Phase 2b study with more than 1,300 subjects.

In 2017, Urovant licensed global rights, excluding Japan and certain Asian territories, for the development and commercialization of vibegron. Urovant initiated EMPOWUR, its international Phase 3 clinical trial for vibegron, in March 2018.

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 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, hMaxi-K, 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 for the treatment of urological conditions and the Company’s expectations regarding its clinical programs for vibegron.

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 Company’s limited operating history and the fact that it has never generated any

product revenue; the Company's ability to achieve or maintain profitability in the future; the Company's dependence on the success of its lead product candidate, vibegron; the Company's reliance on its key scientific, medical or management personnel and on certain affiliates to provide certain services to the Company; risks related to clinical trials, including uncertainties relating to the success of the Company's clinical trials for vibegron and hMaxi-K and any future therapy or product candidates; uncertainties surrounding the regulatory landscape that governs gene therapy products; the Company's dependence on Merck Sharp & Dohme Corp. and Ion Channel Innovations, LLC to have accurately reported results and collected and interpreted data related to vibegron and hMaxi-K prior to the Company's acquisition of the rights related to these product candidates; reliance on third parties to conduct, supervise and monitor the Company's clinical trials; reliance on a single supplier for the enzyme used to manufacture vibegron; the ability to obtain, maintain and enforce intellectual property protection for the Company's technology and products; risks related to significant competition from other biotechnology and pharmaceutical companies; the failure to achieve the market acceptance necessary for commercial success for a product candidate; the Company's ability to satisfy future funding needs on commercially reasonable terms and conditions if at all; 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 final prospectus dated September 26, 2018 filed with the SEC on September 27, 2018, 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

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