Urovant Sciences Announces Publication of Phase 2b Data for Vibegron in European Urology

November 1, 2018

BASEL, Switzerland & IRVINE, Calif.--(BUSINESS WIRE)--Nov. 1, 2018-- Urovant Sciences (Nasdaq: UROV), a clinical-stage biopharmaceutical company focused on developing novel therapies for urologic conditions, today announced the publication of positive results from the international Phase 2b study of vibegron, an investigational oral beta-3 adrenergic agonist being studied for adults with symptoms of overactive bladder (OAB).

The study, which demonstrated once-daily vibegron was well-tolerated and improved OAB symptoms, was published online by *European Urology*, a peer-reviewed medical journal and official journal of the European Association of Urology.

The international, randomized double-blind, placebo-controlled Phase 2b study including an active comparator enrolled more than 1,300 patients with OAB symptoms including frequent urination, sudden urge to urinate, and urge incontinence (leakage). In the two-part trial, patients were first randomized to once-daily oral vibegron monotherapy (3 mg, 15 mg, 50 mg or 100 mg); tolterodine extended release (4 mg); or placebo for eight weeks. In part two, patients were randomized to monotherapy, combination therapy or placebo and received either vibegron (100 mg); tolterodine (4 mg); combination vibegron (100 mg) and tolterodine (4 mg); or placebo for four weeks.

In part one, patients randomized to vibegron 50 mg and 100 mg had clinically and statistically significant decreases in the daily number of micturitions, urgency urinary incontinence episodes, total incontinence episodes and urgency episodes at week 8, versus placebo. Moreover, as early as week 2, treatment with both vibegron 50 mg and vibegron 100 mg was associated with statistically significant decreases compared to placebo across all of these key overactive bladder endpoints. Vibegron was generally well-tolerated and there were no meaningful differences in incidence or severity of adverse events observed between the treatment groups and placebo. In part two of the study, the efficacy of vibegron monotherapy on the primary endpoint – reduction in micturitions – was statistically significant and similar to results observed in part one. The incidence of dry mouth was higher among patients treated with tolterodine alone or given concomitantly with vibegron, versus those treated with vibegron monotherapy.

In 2017, Urovant licensed global rights, excluding Japan and certain Asian territories, for the development and commercialization of vibegron. Earlier this year, Urovant initiated an international Phase 3 clinical program to evaluate the efficacy and safety of vibegron in adults with symptoms of OAB. Vibegron is investigational and has not been approved by the U.S. Food and Drug Administration.

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. www.urovant.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Urovant's plans to advance the clinical development of vibegron, report results of its Phase 3 clinical trial, and develop additional treatments for urologic diseases. 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; and our intellectual property position, including the ability to identify and in-license or acquire third-party patents and licenses, and associated costs. Vibegron is investigational and has not been approved by the U.S. Food and Drug Administration. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Urovant's Registration Statement on Form S-1, which was filed with the Securities and Exchange Commission ("SEC") and declared effective by the SEC on September 26, 2018, as well as any other future filings with the SEC available at www.sec.gov.

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.

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

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