Urovant Sciences Initiates Part 2 of Phase 3 COURAGE Study of Vibegron for Overactive Bladder in Men with Benign Prostatic Hyperplasia

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IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Oct. 21, 2019-- Urovant Sciences (Nasdaq: UROV), a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions, today announced that it will be initiating part 2 of the COURAGE study, an international phase 3 trial to evaluate the safety and efficacy of vibegron for the treatment of symptoms of overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH).

“We are pleased to announce that, after reviewing the safety data from part 1 of the COURAGE trial, the independent Data Safety Monitoring Board (DSMB) agreed that the trial can now move to part 2, which will assess both efficacy and safety of vibegron in men with OAB and BPH,” said Dr. Cornelia Haag-Molkenteller, Chief Medical Officer of Urovant. “This is a pivotal milestone for this development program as there are currently no FDA-approved products specifically indicated for the treatment of overactive bladder in men with BPH.”

About the COURAGE Phase 3 Trial

The COURAGE study is a randomized, double blind, placebo-controlled trial in men who are experiencing OAB symptoms, while also taking BPH medications. For part 2 of the trial, approximately 1,000 male patients with OAB and BPH will be randomized to receive either 75 mg of vibegron or placebo daily for 24 weeks. The co-primary endpoints are the reduction from baseline in average number of micturitions and urgency episodes per 24 hours. Key secondary endpoints are reduction in nocturia episodes (awakening at night to void), prostate symptom scores, and safety.

About Urovant Sciences

Urovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Urovant recently reported positive long-term data for its lead product candidate, vibegron, an oral, once-daily small molecule beta-3 agonist being evaluated for overactive bladder (OAB). The extension of the 12-week pivotal phase 3 EMPOWUR study demonstrated a favorable long-term safety and tolerability profile for vibegron and further improved treatment benefit on key overactive bladder (OAB) symptoms over the 40-week extension period. In addition, vibegron is being evaluated in a phase 3 study for the treatment of OAB in men with benign prostatic hyperplasia and in a phase 2a study for abdominal pain associated with irritable bowel syndrome. 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 Sciences, a subsidiary of Roivant Sciences, Ltd., intends to develop novel treatments for additional urologic diseases. Learn more about us at 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 Urovant’s plans to advance the clinical development of vibegron in patients with OAB and BPH and the advancement of its COURAGE study. 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; our intellectual property position, including the ability to identify and in-license or acquire third-party patents and licenses, and associated costs; 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 most recently filed Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q filed with the SEC, as such risk factors may be amended, supplemented or superseded from time to time by other filings with the SEC. 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.

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