Urovant Sciences Initiates Phase 3 Clinical Program with Vibegron for Overactive Bladder in Men with Benign Prostatic Hyperplasia

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IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Mar. 27, 2019-- Urovant Sciences (Nasdaq: UROV),a clinical-stage biopharmaceutical company developing and commercializing innovative therapies for urologic conditions, today announced that it has initiated COURAGE, an international Phase 3 trial to evaluate the safety and efficacy of vibegron for symptoms of overactive bladder (OAB) in men who are receiving pharmacological treatment for benign prostatic hyperplasia (BPH). Vibegron is an investigational beta-3 agonist that has previously been evaluated in Phase 2b and Phase 3 studies in patients with overactive bladder.

“There are limited clinical data available in men who are taking medications for symptoms associated with benign prostatic hyperplasia, yet continue to experience overactive bladder symptoms,” said Dr. Cornelia Haag-Molkenteller, Chief Medical Officer of Urovant.

An estimated 4.5 million men in the United States are being treated for BPH[1], however half of them also have OAB symptoms.[2] Medications used to treat BPH do not address OAB symptoms. Anticholinergics, a class of medication prescribed for OAB symptoms, are not indicated for OAB symptoms in men receiving pharmacological treatment for BPH and carry risks, including urinary retention, for these patients.[3]

“COURAGE is an important development program for vibegron as there is currently no FDA-approved treatment specifically indicated for men with OAB who are already on a BPH medication,” Dr. Haag-Molkenteller continued. “Based on our discussions with the FDA, we believe that this study could serve as the basis for a New Drug Application submission for vibegron in this indication.”

About the COURAGE Phase 3 Trial

The COURAGE study is a randomized, double blind, placebo-controlled trial in men with BPH who are also taking BPH medications but continue experiencing OAB symptoms. The study will be conducted in two phases, with the first phase focusing on safety and the second phase assessing efficacy and safety. Approximately 1,000 patients who meet eligibility requirements will be randomized to receive either 75 mg of vibegron or placebo daily for 24 weeks.

The co-primary efficacy endpoints will be measured at 12 weeks and include:

- Change from baseline in the average number of micturitions per 24 hours
- Change from baseline in the average number of urgency episodes per 24 hours

Secondary endpoints include change from baseline in the average number of nocturia episodes per night, which is awakening at night to use the bathroom to urinate.

The duration for the double-blind study is 24 weeks. In addition, a 28-week open-label extension study will evaluate the long-term safety and efficacy of vibegron in men with OAB symptoms and on another therapy for BPH. Adverse events will be monitored throughout the trial. The 75 mg dose is the same dose tested in the international EMPOWUR Phase 3 trial for vibegron in patients with OAB. The Company recently announced positive topline results from the pivotal Phase 3 EMPOWUR study.

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.

About Roivant Sciences

Roivant aims to improve health by rapidly delivering innovative medicines and technologies to patients. Roivant does this by building Vants – nimble, entrepreneurial biotech and healthcare technology companies with a unique approach to sourcing talent, aligning incentives, and deploying technology to drive greater efficiency in R&D and commercialization. For more information, please visit www.roivant.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,” “suggest,” “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, the Company’s initiation of the COURAGE study, as well as the plan to develop vibegron for symptoms of OAB in men who are receiving pharmacological treatment for BPH.

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. IMS Health NPA Market Dynamics (2014)
2. Eapen, et al., Res Rep Urol. 2016
3. MacDiarmid SA, et al. Mayo Clinical Proceedings. 2008; 83(9):1002-1010

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