Urovant Sciences Initiates Patient Enrollment in Phase 2a Study of URO-902

December 23, 2019

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Dec. 23, 2019-- Urovant Sciences (Nasdaq: UROV), announced today that the first patient has been enrolled in a Phase 2a study evaluating the efficacy and safety of URO-902, a novel gene therapy product, in patients with overactive bladder (OAB) suffering with urge urinary incontinence (UUI).

“We are excited to have enrolled our first patient in our phase 2a study for URO-902. This novel gene therapy has the potential to provide a new alternative for OAB patients who have failed oral pharmacologic therapy. With the initiation of this program, we now have four on-going clinical programs in patients with OAB, OAB+BPH and IBS-pain. We are now looking forward to our next milestone – the filing of our New Drug Application with the FDA for Vibegron in OAB,” said Cornelia Haag-Molkenteller, Chief Medical Officer of Urovant Sciences.

About the Phase 2a Study

The study is a randomized, double blind, placebo-controlled trial that will evaluate the efficacy, safety, and tolerability of a single administration of URO-902, a novel gene therapy being developed for patients with OAB who have failed oral pharmacologic therapy. URO-902 is administered via direct intradetrusor injections into the bladder wall under local anesthesia in patients who are experiencing OAB symptoms and UUI.

The Phase 2a trial is expected to enroll approximately 80 female patients in two cohorts: the first cohort will receive either a single administration of 24 mg of URO-902 or matching placebo, and the second cohort will receive 48 mg of URO-902 or matching placebo into the bladder wall. Patients will be followed for up to 48 weeks after initial administration. The primary outcome measure is the change in the average daily number of UUI episodes from baseline at week 12, as well as assessing the safety and tolerability of this new potential therapy.

About URO-902

URO-902 has the potential to be the first gene therapy for patients with OAB. This innovative treatment has the potential to address an unmet need for patients who have failed oral pharmacologic therapies and are concerned with potential urinary retention or surgical interventions related to existing third-line OAB treatments.

About Urovant Sciences

Urovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. The Company’s lead product candidate, vibegron, an oral, once-daily small molecule beta-3 agonist is being evaluated for overactive bladder (OAB). Vibegron reported positive data from the 12-week phase 3 pivotal EMPOWUR study and demonstrated favorable longer-term efficacy, safety, and tolerability in a 40 week extension study. The Company plans to file a New Drug Application (NDA) for vibegron for the treatment of OAB by early 2020. Vibegron is also being evaluated for treatment of OAB in men with benign prostatic hyperplasia (OAB+BPH) and for abdominal pain associated with irritable bowel syndrome (IBS). Urovant’s second product candidate, URO-902, is a novel gene therapy being developed for patients with OAB who have failed oral pharmacologic therapy. Urovant Sciences 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 URO-902 in patients with OAB, as well as the clinical development of vibegron in patients with OAB+BPH and IBS-pain. 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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Source: Urovant Sciences

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