Urovant Sciences Announces Publication of Results from Phase 1 Clinical Trials Evaluating URO-902 Gene Therapy in Patients with Overactive Bladder

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IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Feb. 4, 2020-- Urovant Sciences (Nasdaq: UROV) announced today the publication of the safety and efficacy results of URO-902 in female patients with overactive bladder (OAB) from two double-blind, placebo-controlled randomized Phase 1 trials. The first trial was conducted with instillation therapy and the second trial with direct injections into the bladder wall under local anesthesia. The peer-reviewed publication was published online in *Neurology and Urodynamics*. URO-902, a naked DNA plasmid-based gene therapy administered via injection directly into the bladder, is currently being evaluated as a potential treatment for OAB in an ongoing Phase 2a study in the United States. In the trials, URO-902 was well tolerated and the administration via direct injection procedure demonstrated statistically significant improvement in OAB symptoms.

“This is the first publication of clinical data for a potential novel gene therapy delivered directly to the bladder,” said Dr. Eric Rovner, Professor of Urology at the Medical University of South Carolina and the lead author on the publication. “URO-902 has the potential to be an important new treatment for patients with overactive bladder who have failed oral pharmacologic therapy.”

About the Phase 1 Trials

Two double-blind, placebo-controlled, multicenter Phase 1 trials were performed in female patients with OAB and urodynamically demonstrated detrusor overactivity (DO). The aim of the trials was to demonstrate the safety and potential efficacy of URO-902, which comprises a gene therapy plasmid vector expressing the human big potassium channel α subunit. Among the safety outcomes, there were no clinically relevant or dose-limiting adverse events (AEs) preventing dose escalation during either trial, and no participants withdrew due to AEs.

For efficacy, a significant reduction versus placebo in urgency episodes and number of voids were observed as early as one week after injection. These improvements over placebo were statistically significant and observed over 24 weeks.

The full publication can be accessed online at https://onlinelibrary.wiley.com/doi/10.1002/nau.24272.

About URO-902

URO-902, a gene therapy using a naked DNA plasmid vector, has the potential to be the first gene therapy for patients with OAB delivered directly into the bladder. This novel 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, is an oral, once-daily small molecule beta-3 agonist that is being evaluated for overactive bladder (OAB). Urovant Sciences reported positive data from the vibegron 12-week, Phase 3 pivotal EMPOWUR study and demonstrated favorable longer-term efficacy, safety, and tolerability in a 40-week extension study. The Company submitted a New Drug Application to the FDA seeking approval of vibegron for the treatment of patients with OAB in December 2019. 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, a subsidiary of Sumitomo Dainippon Pharma Co., 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 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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