Urovant Sciences Initiates Patient Enrollment in Phase 2a Clinical Trial for Vibegron in Patients with Abdominal Pain Due to Irritable Bowel Syndrome

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BASEL, Switzerland & IRVINE, Calif.--(BUSINESS WIRE)--Jan. 3, 2019-- Urovant Sciences (Nasdaq: UROV), a clinical-stage biopharmaceutical company focused on developing novel therapies for urologic conditions, announced the company enrolled its first patient in a Phase 2a clinical trial evaluating vibegron in patients with abdominal pain due to irritable bowel syndrome (IBS) on December 31, 2018.

The company's investigational new drug application was recently accepted by the U.S. Food and Drug Administration. There are no currently marketed drugs indicated specifically for IBS-associated pain.[1]

The Phase 2a trial is a double-blind, placebo-controlled study in women with abdominal pain due to IBS with predominant diarrhea (IBS-D) or mixed episodes of diarrhea and constipation (IBS-M). The study is expected to enroll approximately 200 patients in the United States, randomized to receive either 75 mg of vibegron or placebo, administered orally once daily for a 12-week period. The primary endpoint is the proportion of patients who achieve at least a 30 percent improvement in the average worst abdominal pain score at week 12. Other clinical endpoints include Global Improvement Scale ratings, stool symptoms and safety.

Vibegron is an investigational oral beta-3 adrenergic receptor agonist currently being assessed for the treatment of overactive bladder. Urovant recently announced the completion of enrollment in its international Phase 3 clinical trial evaluating the safety and efficacy of vibegron as treatment for adults with symptoms of overactive bladder. Data available to date indicate vibegron is well tolerated. Vibegron has not been approved for commercialization by the U.S. Food and Drug Administration.

Upcoming Investor & Analyst Day

For institutional investors and financial analysts interested in learning more about Urovant, the company invites you to save the date for Urovant's first R&D Day to be held February 7, 2019 in New York. Learn more or register here.

About Irritable Bowel Syndrome Related Pain

Irritable bowel syndrome (IBS) is characterized by recurrent abdominal pain associated with two or more of the following symptoms: defecation, change in stool frequency, and/or change in stool form or appearance. In the United States, approximately 30 million to 40 million have IBS symptoms, 30% of whom consult with a physician.[2] Approximately 80% of these patients identify pain as a symptom contributing to the severity of their IBS[3] and it is estimated 7.2 million to 9.6 million IBS patients suffer from IBS-associated pain[2]. While there are approved therapies for IBS with constipation and IBS with diarrhea, these therapies do not adequately address IBS-associated pain. Moreover, there are no currently marketed drugs indicated specifically for IBS-associated pain.[1]

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.

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 abdominal pain due to IBS and patients with OAB, as well as 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; 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 in the section titled "Risk Factors" set forth in Urovant's Form 10-Q, which was filed with the Securities and Exchange Commission ("SEC") on November 13, 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. International Foundation for Gastrointestinal Disorders, accessed December 14, 2018; https://www.aboutibs.org/treating-ibs-pain.html
2. Canavan C., et al., Clinical Epidemiology 2014
3. Lovell RM, Ford AC, et al., Clin Gastroenterol Hepatol. 2012; Drossman DA, et al., J Clin Gastroenterol 2009

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