Urovant Sciences Licenses Novel Gene Therapy for Overactive Bladder

August 28, 2018

- There are no currently available FDA-approved gene therapy treatments for overactive bladder
- Urovant expects to initiate Phase 2 hMaxi-K study in 2019

BASEL, Switzerland and IRVINE, Calif., August 28, 2018/PRNewswire – Urovant Sciences, a clinical-stage biopharmaceutical company focused on developing therapies for urologic conditions, today announced it has licensed a novel investigational gene therapy for patients with overactive bladder (OAB) symptoms who have failed oral pharmacologic therapy.

Urovant has licensed global rights for the development and commercialization of hMaxi-K from Ion Channel Innovations. There are no currently available FDA-approved gene therapy treatments for overactive bladder.

hMaxi-K has been evaluated in two Phase 1 studies in OAB patients including a small, double-blind, placebo-controlled Phase 1b clinical trial as an intravesical injection in women with overactive bladder symptoms. Ion Channel Innovations completed the Phase 1b study in 2017 and found hMaxi-K to be generally well tolerated. Clinical results of the trial, which included a limited number of patients (n=13), indicated dose-dependent improvements in urinary urgency and frequency, achieving statistical significance ($p<0.05$) in the high dose cohort.

“We are pleased to add the gene therapy hMaxi-K to our clinical development portfolio. We are eager to study the potential of hMaxi-K as an alternative therapy for OAB patients who are not getting adequate relief from other therapies,” said Keith A. Katkin, President and Chief Executive Officer of Urovant. “Urovant also has access to gene therapy expertise through the Roivant family of companies.”

Urovant plans to meet with the FDA and initiate a Phase 2 clinical study in 2019 to investigate hMaxi-K as a novel treatment for OAB patients who have not responded to other pharmacological therapies.

Earlier this year, Urovant initiated a Phase 3 clinical trial program for vibegron, an investigational oral β3-adrenergic agonist being studied as a second-line treatment in adults with symptoms of OAB. Urovant expects to report top-line results for its Phase 3 trial of vibegron next year.

About Overactive Bladder
Overactive bladder is a clinical condition characterized by the sudden urge to urinate, with or without accidental urinary leakage, and usually with increased frequency. The exact cause is unknown, making this a difficult condition to treat. In the United States, more than 30 million people over the age of 40 suffer from the bothersome symptoms of OAB[1], which can lead to depression and anxiety and have a negative impact on quality of life.[2]

About Urovant Sciences
Urovant is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Urovant’s lead product candidate, vibegron, is a selective β3-adrenergic agonist being developed for an oral, once-daily treatment for overactive bladder 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 intends to develop treatments for additional urologic diseases. For more information, please visit urovant.com.

Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding Urovant’s plans to advance the clinical development of hMaxi-K and vibegron. 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 product 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 hMaxi-K and vibegron, including reliance on collaboration partners and the ability to procure additional sources of financing; and our intellectual property position including the ability to identify and in-license or acquire third-party patents and licenses, and associated costs. hMaxi-K and vibegron are investigational and have not been approved by the U.S. Food and Drug Administration.

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. Coyne, et al., EpiLUTS 2007
2. Kinsey D, et al., J Health Psychol. 2016

Contacts

Investor inquiries: Investors@Urovant.com

Media inquiries: Media@Urovant.com