Urovant Sciences Announces Positive Topline Results of Phase 2a Trial of its Potential Novel Gene Therapy, URO-902

March 7, 2022

Study showed clinically meaningful impact on common symptoms of overactive bladder (OAB) compared to placebo from baseline to week 12

IRVINE, Calif. & BASEL, Switzerland – March 7, 2022 – Urovant Sciences, a wholly-owned subsidiary of Sumitovant Biopharma Ltd., today announced positive topline results from its Phase 2a, double-blind, placebo-controlled exploratory study of URO-902, an investigational, novel, locally injected gene therapy product (plasmid human cDNA encoding maxi-K channel), in patients with overactive bladder (OAB), who were not well managed by oral therapies.

"URO-902 showed a clinically meaningful and statistically significant effect on a number of relevant outcome measures in OAB including number of micturitions, urgency episodes, and quality of life indicators compared to placebo, 12 weeks post-administration," said Cornelia Haag-Molkenteller, MD, PhD, executive vice president and chief medical officer of Urovant Sciences. "URO-902 was well tolerated, compared to placebo. The most common adverse event was urinary tract infection, in both treatment groups." We are encouraged by these positive results and pending the completion of the study in Fall 2022 and we look forward to discussing next steps for the URO-902 clinical development plan."

The Phase 2a study included 80 female patients and was designed to evaluate the efficacy, safety, and tolerability of a single, physician administered dose of URO-902 of 24 milligrams (mg) and 48 mg, compared with placebo with a primary timepoint at week 12 post-administration. Patients were followed for up to 48 weeks post-administration. URO-902 has the potential to be the first gene therapy for patients with OAB.

"These promising results suggest that URO-902 could potentially offer a new treatment option for patients with overactive bladder who have been inadequately managed by oral pharmacologic therapy," said Kenneth Peters, MD, principal investigator, and chief of the department of urology at Beaumont Hospital, Royal Oak; Medical director of the Beaumont Women's Urology and Pelvic Health Center and professor and chair of urology of the Oakland University William Beaumont School of Medicine in Rochester, Michigan.

The company plans to present the topline results of the study at the American Urological Association annual meeting being held May 13-16, 2022 in New Orleans, LA.

About the Phase 2a Study

The study was a randomized, double blind, placebo-controlled trial to evaluate the efficacy, safety, and tolerability of a single physician administered dose of URO-902, a novel gene therapy being developed for patients with OAB who have not been adequately managed with oral or transdermal pharmacologic therapy for OAB. URO-902 is administered via direct intradetrusor injections into the bladder wall under local anesthesia in patients who are experiencing OAB symptoms and urge urinary incontinence (UUI).

The Phase 2a trial enrolled 80 female patients in two cohorts: the first cohort received either a single administration of 24 mg of URO-902 or matching placebo, and the second cohort received 48 mg of URO-902 or matching placebo into the bladder wall. Multiple outcome measures were explored, including the effect on the number of micturitions, urgency episodes, and quality of life indicators compared to placebo, 12 weeks post-administration, as well as an assessment of the safety and tolerability of this potential new therapy. Patients were followed for up to 48 weeks after initial administration.

About URO-902

URO-902 has the potential to be the first gene therapy for patients with OAB. If approved, this innovative treatment may address an unmet need for patients who have not been adequately managed by oral or transdermal pharmacologic OAB therapies and are concerned with potential urinary retention with other minimally invasive therapies or surgical interventions related to existing third-line OAB treatments.

About Urovant Sciences

Urovant Sciences is a biopharmaceutical company focused on developing and commercializing innovative therapies for areas of unmet need, with a dedicated focus in Urology. The Company's lead product, GEMTESA ®(vibegron), is an oral, once-daily (75 mg) small molecule beta-3 agonist for the treatment of adult patients with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. GEMTESA was approved by the U.S. FDA in December 2020 and launched in the U.S. in April 2021. GEMTESA is also being evaluated for the treatment of OAB in men with benign prostatic hyperplasia. The Company'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 wholly owned subsidiary of Sumitovant Biopharma Ltd., intends to bring innovation to patients in need in urology and other areas of unmet need. Learn more about us at www.urovant.com or follow us on Twitter or LinkedIn.

About Sumitovant Biopharma Ltd.

Sumitovant is a global biopharmaceutical company leveraging data-driven insights to rapidly accelerate development of new potential therapies for unmet patient conditions. Through our unique portfolio of wholly-owned "Vant" subsidiaries—Urovant, Enzyvant, Spirovant, Altavant—and use of embedded computational technology platforms to generate business and scientific insights, Sumitovant has supported the development of FDA-approved products and advanced a promising pipeline of early-through late-stage investigational assets for other serious conditions. Sumitovant, a wholly-owned subsidiary of Sumitomo Dainippon Pharma, is also the majority-shareholder of Myovant (NYSE: MYOV). For more information, please visit our website at www.sumitovant.com or follow us on Twitter and LinkedIn.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China, and other Asian countries. Sumitomo Dainippon Pharma is based on the 2005 merger between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has more than 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at https://www.ds-pharma.com.

About GEMTESA®

GEMTESA is a prescription medicine for adults used to treat the following symptoms due to a condition called overactive bladder:

- urge urinary incontinence: a strong need to urinate with leaking or wetting accidents
- urgency: the need to urinate right away
- frequency: urinating often

It is not known if GEMTESA is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Do not take GEMTESA if you are allergic to vibegron or any of the ingredients in GEMTESA.

Before you take GEMTESA, tell your doctor about all your medical conditions, including if you have liver problems; have kidney problems; have trouble emptying your bladder or you have a weak urine stream; take medicines that contain digoxin; are pregnant or plan to become pregnant (it is not known if GEMTESA will harm your unborn baby; talk to your doctor if you are pregnant or plan to become pregnant); are breastfeeding or plan to breastfeed (it is not known if GEMTESA passes into your breast milk; talk to your doctor about the best way to feed your baby if you take GEMTESA).

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

What are the possible side effects of GEMTESA?

GEMTESA may cause serious side effects including the inability to empty your bladder (urinary retention). GEMTESA may increase your chances of not being able to empty your bladder, especially if you have bladder outlet obstruction or take other medicines for treatment of overactive bladder. Tell your doctor right away if you are unable to empty your bladder.

The most common side effects of GEMTESA include headache, urinary tract infection, nasal congestion, sore throat or runny nose, diarrhea, nausea and upper respiratory tract infection. These are not all the possible side effects of GEMTESA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please click here for full Product Information for GEMTESA.

Urovant Sciences
Alana Darden Powell
Vice President, Corporate Communications
949-436-3116
alana.darden@Urovant.com
media@urovant.com

Sumitovant Biopharma
Maya Frutiger
Head of Corporate Communications
media@sumitovant.com

Source: Urovant Sciences, Inc.