Urovant Sciences Announces Progression of URO-902 Phase 2a Trial Following Positive Recommendation from the Data and Safety Monitoring Board

February 11, 2021

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Feb. 11, 2021-- Urovant Sciences (Nasdaq: UROV) announced today that the independent Data and Safety Monitoring Board (DSMB) has recommended the continuation of the phase 2a study of URO-902, a novel gene therapy product, in patients with overactive bladder (OAB) and urge urinary incontinence (UUI).

URO-902 has the potential to be the first gene therapy for patients with OAB. Following the recommendation of the DSMB, Urovant is proceeding with opening cohort 2 of the study with a dose of 48 mg or placebo.

About the Phase 2a Study

This randomized, double blind, placebo-controlled study 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 received either a single administration of 24 mg of URO-902 or matching placebo into the bladder wall, 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 biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. The Company's lead product, GEMTESA® (vibegron), is an oral, once-daily (75 mg) small molecule beta-3 agonist approved by the U.S. FDA in December 2020 for the treatment of adult patients with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency. GEMTESA is also being evaluated for the treatment of OAB in men with benign prostatic hyperplasia (OAB+BPH). 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 subsidiary of Sumitomo Dainippon Pharma Co., Ltd., intends to develop novel treatments for additional urologic diseases. Learn more about us at www.urovant.com.

About Sumitovant Biopharma Ltd.

Sumitovant is a global biopharmaceutical company with offices in New York City and London. Sumitovant is a wholly owned subsidiary of Sumitomo Dainippon Pharma. Sumitovant is the majority shareholder of Myovant Sciences and Urovant Sciences, and wholly owns Enzyvant Therapeutics, Spirovant Sciences, and Altavant Sciences. Sumitovant's promising pipeline is comprised of early-through late-stage investigational medicines across a range of disease areas targeting high unmet need. For further information about Sumitovant, please visit https://www.sumitovant.com.

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 the European Union. 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 6,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at https://www.ds-pharma.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. 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 and cost of Urovant's efforts to commercialize vibegron; Urovant's ability to realize the anticipated benefits of the co-promotion agreement with Sunovion in the manner or timeline expected; Urovant's reliance on Sunovion for the co-promotion and distribution of vibegron and Urovant's ability to secure alternative access to commercial infrastructure or strategic collaborations for the commercialization or distribution of products if it is unable to continue the relationship with Sunovion; 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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