



Urovant Sciences Announces Positive Clinical Efficacy and Safety Data from Vibegron EMPOWUR Long Term Extension Study

November 19, 2020

Extension study demonstrates favorable results in long term treatment of overactive bladder with vibegron, including improvements in incontinence efficacy, quality of life endpoints and with good tolerability

Long term EMPOWUR extension study data featured in an oral presentation at the virtual International Continence Society (ICS) Annual Meeting

Meta-analysis on increased risk of incident dementia following use of anticholinergics will also be presented at ICS

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Nov. 19, 2020-- Urovant Sciences (Nasdaq: UROV) today announced positive efficacy and safety data from the vibegron EMPOWUR long term extension study with patient data over a total exposure of 52 weeks. The data demonstrate that vibegron improved quality of life (QoL) and incontinence efficacy endpoints with good long term tolerability in adult patients with overactive bladder (OAB) and symptoms of urge urinary incontinence (UUI), urgency and urinary frequency.

Vibegron is a once-daily, beta-3 adrenergic agonist under investigation for the treatment of OAB by the U.S. Food and Drug Administration (FDA). In March 2020, the FDA accepted the New Drug Application (NDA) for vibegron in OAB and assigned a Prescription Drug User Fee Act (PDUFA) goal date of December 26, 2020.

In an [oral presentation](#) at the virtual International Continence Society (ICS) Annual Meeting, David Staskin, MD, presented results from the 40-week EMPOWUR extension to the 12-week EMPOWUR trial that show 75 mg of vibegron was well tolerated over the total exposure of 52 weeks and demonstrated numerically greater improvements from baseline compared with tolterodine across QoL and responder efficacy endpoints. These results are consistent with the results from the placebo-controlled EMPOWUR phase 3 study, with comparable safety and durable efficacy.

"A large segment of the OAB population suffers in silence because they are embarrassed, afraid, or unaware that there are treatments, including medications, that could address their problems with bladder control. This situation leads to OAB being overlooked and undertreated, and highlights the need for therapeutic options to improve quality of life," said Dr. Staskin, principal investigator of the EMPOWUR study, leading urologist with St. Elizabeth's Medical Center, and Associate Professor of Urology at Tufts University School of Medicine, Boston. "The EMPOWUR 40-week extension study demonstrated how vibegron, if approved by the FDA, has the potential to offer a lasting solution for adult patients with OAB to manage urinary frequency and urinary incontinence associated with the urgent need to go to the bathroom."

At week 52, 61 percent of 143 vibegron-treated patients had a ≥ 75 percent reduction and 40.8 percent showed a 100 percent reduction in UUI (urge urinary incontinence), a key symptom for OAB patients. In addition, 71.1 percent had ≥ 50 percent reduction in total incontinence episodes from baseline to week 52. In this same time period, vibegron demonstrated numerically greater improvements from baseline versus tolterodine for all QoL subscale scores as measured by the Overactive Bladder Questionnaire Long Form (OAB-qLF), including coping, concern, sleep, social interaction, health-related QoL and symptom bother. Vibegron 75 mg once daily demonstrated a 40-week safety profile comparable to that of 12-week EMPOWUR study, as well as durable efficacy for QoL and incontinence efficacy endpoints. Adverse events (AEs) occurred in 62.6% (171/273) of vibegron and 54.3% (126/232) of tolterodine patients; 4 (1.5%) vibegron and 8 (3.4%) tolterodine patients discontinued study medication due to an AE.

Examining the Risk of Cognitive Effects Associated with Anticholinergic Agents

On November 20, there will be a presentation of findings from a [recent meta-analysis of anticholinergic use](#) by Dr. Roger Dmochowski, which was supported by Urovant. The systemic literature review and meta-analysis revealed that use of anticholinergic agents for three months or longer increased the risk of incident dementia by an average of 46 percent relative to non-use. This increased risk also was reported in the six studies included in the meta-analysis that evaluated anticholinergic medications used to treat overactive bladder.

Anticholinergic medications are currently the most frequently prescribed pharmaceutical treatment for OAB. They exert their effects by blocking the action of the neurotransmitter acetylcholine and are prescribed to treat a wide range of medical conditions.

"The findings from our systematic literature review and meta-analysis shine a light on what data and anecdotal evidence has demonstrated for many practicing physicians: ongoing use of anticholinergics to treat OAB comes with an increased risk," said Dr. Dmochowski, associate surgeon in chief and Professor of Urologic Surgery at Vanderbilt University Medical Center. "These findings underscore the need for medicines that can treat conditions such as OAB without the potential cognitive risks associated with anticholinergic agents. It is essential that health care providers work with their patients to determine an appropriate treatment plan."

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.

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 vibegron in patients with OAB, including related to the status of potential FDA approval. 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 FDA's potential approval of vibegron and the associated package insert; 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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