Urovant Sciences Announces Co-Promotion Agreement for Vibegron with Sunovion Pharmaceuticals

October 7, 2020

Agreement will supplement Urovant's targeted sales and market access efforts in the launch of vibegron by expanding the outreach to Primary Care Physicians and their patients

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Oct. 7, 2020-- Urovant Sciences (Nasdaq: UROV) today announced it has entered into a five-year U.S. co-promotion agreement with Sunovion Pharmaceuticals Inc. to promote vibegron in the primary care segment upon receiving U.S. Food and Drug Administration (FDA) approval for the drug. In March 2020, the FDA accepted the New Drug Application (NDA) for vibegron in overactive bladder (OAB) and assigned a Prescription Drug User Fee Act (PDUFA) goal date of December 26, 2020.

Under the terms of the agreement, Sunovion will deploy its multi-specialty sales force to bring vibegron to primary care physicians (PCP). In support of this effort, Sunovion will provide sales and marketing activities targeting the PCP segment through March 31, 2026. In compensation for its sales and marketing activities during the period of this agreement, Sunovion will receive a mid-single digit repayment fee based on the net sales of vibegron beginning on April 1, 2023.

"The co-promotion agreement with Sunovion significantly expands our planned commercial footprint for vibegron as we look forward to the potential approval and launch of vibegron in the coming months. While Urovant sales representatives will be focused on urologists, long-term care, and high-prescribing PCPs, the Sunovion team will significantly broaden our reach into the U.S. primary care community," said Walt Johnston, Urovant's Senior Vice President of Commercial. "This is a great example of the strategic benefit of our affiliation with the Sumitomo Dainippon Pharma Group of companies. This partnership allows us to reach the PCP community without incurring any cash outlay through March 2023."

"We are pleased to deepen our commercial relationship with Urovant," said Thomas Gibbs, SVP and Chief Commercial Officer of Sunovion. "Together, we expect to accelerate Urovant's path forward by leveraging Sunovion's sales expertise and infrastructure for co-promotion activities within the primary care specialty."

The co-promotion agreement is in addition to the exclusive three-year agreement Urovant entered into with Sunovion in June 2020 for services related to wholesale trade and retail distribution, contract operations, and select account management activities for vibegron. Sunovion Pharmaceuticals Inc. is a subsidiary of Sumitomo Dainippon Pharma Co., Ltd., which is the majority shareholder of Urovant.

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 Sunovion Pharmaceuticals Inc.

Sunovion is a global biopharmaceutical company focused on the innovative application of science and medicine to help people with serious medical conditions. Sunovion's vision is to lead the way to a healthier world. The company's spirit of innovation is driven by the conviction that scientific excellence paired with meaningful advocacy and relevant education can improve lives. With patients at the center of everything it does, Sunovion has charted new paths to life-transforming treatments that reflect ongoing investments in research and development and an unwavering commitment to support people with psychiatric, neurological and respiratory conditions.

Headquartered in Marlborough, Mass., Sunovion is an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd. Sunovion Pharmaceuticals Europe Ltd., based in London, England, and Sunovion Pharmaceuticals Canada Inc., based in Mississauga, Ontario, are wholly-owned direct subsidiaries of Sunovion Pharmaceuticals Inc. Additional information can be found on the company's web sites: www.sunovion.com, www.sunovion.eu and www.sunovion.ca. Connect with Sunovion on Twitter, LinkedIn, Facebook and YouTube.

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 Urovant and Myovant, and wholly owns Enzyvant, Spirovant, and Altavant. 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 U.S. FDA approval of vibegron in patients with OAB, Urovant's planned commercial footprint for vibegron and Urovant's expectations regarding access to the PCP market. 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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