



## Urovant Sciences Announces Submission of New Drug Application for Vibegron for the Treatment of Overactive Bladder

December 30, 2019

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Dec. 30, 2019-- Urovant Sciences (Nasdaq: UROV) announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval of once-daily 75mg vibegron for the treatment of patients with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

The NDA for vibegron is supported by an extensive clinical development program, which included over 4,000 patients with OAB. In a pivotal efficacy and safety study, once-daily 75mg vibegron met all primary and key secondary efficacy endpoints, and demonstrated a favorable safety profile.

"Our NDA submission for vibegron is a significant milestone for our company and brings us one step closer to potentially providing a new oral therapy to a highly dissatisfied market," said Keith Katkin, Chief Executive Officer of Urovant. "The symptoms of overactive bladder affect over 30 million people in the U.S. Vibegron, if approved next year, would be the first new branded prescription drug for the treatment of OAB in nearly a decade."

### About Vibegron:

Vibegron is a once-daily beta-3 adrenergic agonist under investigation for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

### 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, an oral, once-daily small molecule beta-3 agonist is being evaluated for overactive bladder (OAB). Vibegron reported positive data from the 12-week phase 3 pivotal EMPOWUR study and demonstrated favorable longer-term efficacy, safety, and tolerability in a 40-week extension study. 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](http://www.urovant.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 merger in 2005 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 and obtain 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 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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Source: Urovant Sciences

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