# Kyorin Receives Approval from Japan's Ministry of Health, Labour and Welfare for Vibegron for Overactive Bladder

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- Kyorin secures first commercial approval for vibegron
- Vibegron will be a new treatment option in Japan, where an estimated 10.4 million people suffer from overactive bladder symptoms defined as the sudden urge to urinate, frequent urination and urge incontinence

BASEL, Switzerland and IRVINE, Calif., Sept. 24, 2018 /PRNewswire/ — Urovant Sciences, a clinical-stage biopharmaceutical company focused on developing novel therapies for urologic conditions, today announced that Kyorin Pharmaceutical Co., Ltd. (Kyorin) received marketing approval from Japan's Ministry of Health, Labour and Welfare for vibegron for the treatment of adults with overactive bladder (OAB) in Japan.

Kyorin licensed vibegron for Japan from Merck & Co., Inc. in 2014, and later expanded the license to include certain other Asian countries in 2017. Urovant licensed rights to vibegron for the United States and the rest of the world from Merck, Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. in 2017 and subsequently entered into a collaboration agreement with Kyorin later that year. Under the collaboration agreement, Urovant and Kyorin share information related to the development of vibegron, including clinical trial and nonclinical study data.

Kyorin developed vibegron for Japan and submitted its marketing application to Japan's Pharmaceuticals and Medical Devices Agency in September 2017. In Kyorin's Phase 3 clinical trial, vibegron demonstrated a significant reduction in frequency of urination, urgency episodes, urinary urge incontinence episodes and total incontinence episodes. Vibegron also was observed to be well tolerated in Kyorin's Phase 3 program.

"Kyorin's approval of vibegron in Japan will address a substantial need and bring patients with OAB in Japan a new treatment option to discuss with their physician," said Keith Katkin, President and Chief Executive Officer of Urovant. "We are making significant progress with our international Phase 3 clinical trial and look forward to reporting top-line results next year."

Urovant initiated its international pivotal Phase 3 clinical trial of vibegron in adults with OAB earlier this year. Vibegron is investigational in the United States and has not been approved by the U.S. Food and Drug Administration.

**About Overactive Bladder**
Overactive bladder is a clinical condition characterized by the sudden urge to urinate that is difficult to control (urgency), with or without accidental urinary leakage (urge urinary incontinence), and usually with increased frequency of urination. The exact cause is unknown, making this a difficult condition to treat. In the United States, more than 30 million people over the age of 40 suffer from the bothersome symptoms of OAB[1], which can lead to depression, anxiety and a negative impact on quality of life.[2]

**About Urovant Sciences**
Urovant is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Urovant's lead product candidate, vibegron, is an oral, once-daily, small molecule beta-3 agonist being evaluated for the treatment of OAB with symptoms of urge urinary incontinence, urgency and urinary frequency. Urovant has licensed global rights, excluding Japan and certain Asian territories, for the development and commercialization of vibegron. Urovant's second product candidate, hMaxi-K, is a novel gene therapy being developed for patients with OAB who have failed oral pharmacological therapy. Urovant intends to develop treatments for additional urologic diseases. For more information, please visit www.urovant.com.

**Forward-Looking Statements**
This press release contains forward-looking statements, including statements regarding Urovant's plans to advance the clinical development of vibegron, report results of its Phase 3 clinical trial, and develop additional treatments for urologic diseases. 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; and our intellectual property position, including the ability to identify and in-license or acquire third-party patents and licenses, and associated costs. Vibegron is investigational and has not been approved by the U.S. Food and Drug Administration.

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.

For the estimate of individuals in Japan who suffer from symptoms of overactive bladder, see Clinical Guidelines for Overactive Bladder Syndrome 2nd Edition, Japanese Continence Society

1. Coyne, et al., EpiLUTS 2007
2. Kinsey D, et al., J Health Psychol. 2016

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