Urovant Sciences Parent Company, Roivant Sciences, and Sumitomo Dainippon Pharma Enter into a Memorandum of Understanding to Create Broad Strategic Alliance

September 6, 2019

- Sumitomo Dainippon Pharma is expected to fully assume Roivant's ownership interest of Urovant Sciences (approximately 75% of outstanding Urovant shares); definitive agreement expected by the end of October 2019
- Sumitomo Dainippon Pharma is a top-ten Japanese listed multi-national pharmaceutical company with an extensive history of innovation in drug development and commercialization. Sumitomo Dainippon Pharma has over 6,000 employees and generated over $4 billion in revenue last year through commercialization of several large market pharmaceutical drugs in the U.S., including the blockbuster drug LATUDA®
- Upon close, this transaction will provide Urovant Sciences with a global platform, enhanced commercialization resources and infrastructure, including, but not limited to, managed care, drug distribution, and manufacturing

IRVINE, Calif. & BASEL, Switzerland--(BUSINESS WIRE)--Sep. 6, 2019-- Urovant Sciences (Nasdaq: UROV) today announced that its parent company, Roivant Sciences, and Sumitomo Dainippon Pharma Co., Ltd. (TSE: 4506), a leading global Japanese pharmaceutical company, have entered into a non-binding memorandum of understanding for the creation of a significant multi-national Sumitomo Dainippon-Roivant Alliance ("Alliance") that will include Roivant's ownership interests in Urovant Sciences and four additional biopharmaceutical "Vant" companies. Roivant will collaborate with Sumitomo Dainippon Pharma, with continued involvement of Roivant's senior leaders, to ensure the success of the Alliance and the continued support of Urovant Sciences in its mission to develop and commercialize innovative therapies for urologic conditions. Roivant and Sumitomo Dainippon Pharma expect to sign the definitive agreement for their Strategic Alliance by the end of October 2019. The transaction will be subject to customary closing conditions and any required governmental approvals.

Sumitomo Dainippon Pharma plans to support the commercialization of vibegron by leveraging the potential benefits of scale of Sumitomo Dainippon Pharma's global commercial infrastructure including but not limited to, market access, drug distribution and manufacturing.

"We look forward to this promising new Alliance which provides significant advantages for us as we prepare for the commercial launch of vibegron," said Keith Katkin, CEO of Urovant. "Our planned NDA filing and launch preparation for vibegron are well underway and will benefit from the partnership of a large, successful multi-national company. In addition, we are excited to have the strategic infrastructure support and proven commercial resources of Sumitomo Dainippon. This relationship should greatly enhance Urovant Sciences' commercial approach to the US market, strengthens supply chain capabilities and should allow Urovant to fully optimize its launch plan for vibegron."

Earlier this year, Urovant Sciences announced positive top-line data from the pivotal Phase 3 EMPOWUR trial evaluating vibegron in adults with symptoms of overactive bladder (OAB). Urovant Sciences is planning to submit a New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) by early 2020. Urovant Sciences has also completed enrollment in Part 1 of its two-part Phase 3 study evaluating vibegron for symptoms of overactive bladder (OAB) in men who are receiving pharmacological treatment for benign prostatic hyperplasia (BPH). In addition, Urovant Sciences is enrolling a Phase 2 study evaluating the treatment of vibegron in patients with abdominal pain related to IBS and also expects to start patient enrollment in a Phase 2a trial evaluating novel gene therapy product URO-902 in patients with OAB by the end of the fourth quarter of 2019.

About Urovant Sciences

Urovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Urovant recently reported positive Phase 3 trial results for its lead product candidate, vibegron, an oral, once-daily small molecule beta-3 agonist being evaluated for overactive bladder (OAB). The international, pivotal trial achieved both co-primary endpoints and all seven key secondary endpoints. In addition, vibegron is being evaluated in a Phase 3 study for the treatment of OAB in men with benign prostatic hyperplasia and in a Phase 2a study for abdominal pain associated with irritable bowel syndrome. Urovant's second product candidate, URO-902, is a novel gene therapy being developed for patients with OAB who have failed oral pharmacological therapy. Urovant Sciences, a subsidiary of Roivant Sciences, Ltd., intends to develop novel treatments for additional urologic diseases. Learn more about us at www.urovant.com.

About Roivant Sciences

Roivant aims to improve health by rapidly delivering innovative medicines and technologies to patients. Roivant does this by building Vants – nimble, entrepreneurial biotech and healthcare technology companies with a unique approach to sourcing talent, aligning incentives, and deploying technology to drive greater efficiency in R&D and commercialization. Roivant today is comprised of a central technology-enabled platform and 20 Vants with over 45 investigational medicines in clinical and preclinical development and multiple healthcare technologies. For more information, please visit www.roivant.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 Roivant Sciences and Sumitomo Dainippon Pharma's plans with respect to the Alliance, including the timing of entry into the definitive agreement, timing of closing of the Alliance and post-closing management of Urovant; the Company's plans and strategies for the development and commercialization of innovative therapies for the treatment of urological conditions; the Company's expectations regarding its anticipated NDA filing for vibegron for OAB; the Company's expectations regarding its study of vibegron in men with OAB and BPH and its study of vibegron in patients with abdominal pain related to IBS; and the Company's expectations regarding its Phase 2a study for URO-902.

The Company's forward-looking statements are based on management's current expectations and beliefs, and are subject to a number of risks and uncertainties that could lead to actual results differing materially from those projected, forecasted or expected. Although the Company believes that the assumptions underlying these forward-looking statements are reasonable, they are not guarantees and the Company can give no assurance that its expectations will be attained. Factors that could materially affect the Company's operations and future prospects or which could cause actual results to differ materially from expectations include, but are not limited to: the possibility that Roivant and Sumitomo Dainippon Pharma may not enter into a definitive agreement on the terms or timing described in this press release or at all; the possibility that Roivant and Sumitomo Dainippon Pharma may be unable to obtain required governmental approvals or that other conditions to closing the transaction may not be satisfied, such that the transaction will not close or that the closing may be delayed; the potential impact to the Company if the Alliance is deemed to constitute a change in control of the Company, including under its debt and other material agreements and with respect to its tax attributes; the Company's limited operating history and the fact that it has never generated any product revenue; the Company's ability to achieve or maintain profitability in the future; the Company's dependence on the success of its lead product candidate, vibegron; the Company's reliance on its key scientific, medical or management personnel and on certain affiliates to provide certain services to the Company; risks related to clinical trials, including uncertainties relating to the success of the Company's clinical trials for vibegron and URO-902 and any future therapy or product candidates; uncertainties surrounding the regulatory landscape that governs gene therapy products; the Company's dependence on Merck Sharp & Dohme Corp. and Ion Channel Innovations, LLC to have accurately reported results and collected and interpreted data related to vibegron and URO-902 prior to the Company's acquisition of the rights related to these product candidates; reliance on third parties to conduct, supervise and monitor the Company's clinical trials; reliance on a single supplier for the enzyme used to manufacture vibegron; the ability to obtain, maintain and enforce intellectual property protection for the Company's technology and products; risks related to significant competition from other biotechnology and pharmaceutical companies; the failure to achieve the market acceptance necessary for commercial success for a product candidate; the Company's ability to satisfy future funding needs on commercially reasonable terms and conditions if at all; 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. You should not place undue reliance on the forward-looking statements in this press release, which speak only as of the date hereof, and, except as required by law, the Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

The Memorandum is not legally binding with the exception of some stipulations. The two companies will continue to conduct necessary due diligence and engage in mutual consultations as required as they work toward the conclusion of a legally binding definitive agreement concerning detailed conditions, etc. of the Strategic Alliance by the end of October 2019.

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