Roivant Sciences and Takeda Launch Myovant Sciences to Develop Innovative Therapeutics for Women's Health and Prostate Cancer

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- Myovant to conduct global phase 3 programs of relugolix, a potential best-in-class GnRH antagonist for the treatment of uterine fibroids, endometriosis and prostate cancer

- Lynn Seely, MD, former Chief Medical Officer of Medivation, named President & Chief Executive Officer of Myovant Sciences, Inc.

- Pipeline also includes RVT-602 for use in female infertility

OSAKA, Japan and HAMILTON, Bermuda, June 6, 2016 /PRNewswire/ -- Takeda Pharmaceutical Company Limited (TSE: 4502) and Roivant Sciences Ltd. today announced the formation of Myovant Sciences Ltd. ("Myovant"), a biopharmaceutical company focused on delivering innovative women's health and prostate cancer solutions by efficiently advancing new medicines to market that have the potential to improve the lives of millions of patients. In addition, Lynn Seely, MD, an endocrinologist who led the development of XTANDI® (enzalutamide) for the treatment of prostate cancer as the Chief Medical Officer of Medivation from 2005 to 2015, was named the President & Chief Executive Officer of Myovant Sciences, Inc.

Myovant Partnership Summary

Takeda has granted Myovant an exclusive, worldwide license (excluding Japan and certain other Asian countries) to relugolix (TAK-385), a phase 3 drug candidate that has been evaluated in over 1,300 patients to date. Relugolix has successfully demonstrated significant clinical benefit and was generally well-tolerated across multiple, large, randomized phase 2 clinical trials in three different indications. Relugolix is being developed as an oral, once-daily, potential best-in-class gonadotropin-releasing hormone (GnRH) receptor antagonist for uterine fibroids, endometriosis and prostate cancer. Takeda will retain commercial rights for relugolix in Asian countries, including Japan, where Takeda is actively conducting two phase 3 registration studies for the treatment of uterine fibroids. Takeda has also granted Myovant an exclusive, worldwide license to RVT-602 (TAK-448), a novel, oligopeptide kisspeptin receptor agonist as a product candidate for the treatment of infertility in females. Financial terms of the partnership were not disclosed.

"With Takeda strengthening its focus around the core therapeutic areas of oncology, gastroenterology and central nervous system diseases, as well as establishing a strategy that embraces innovative partnerships, it is important that we seek alternatives to further develop and create value around promising assets that are either outside these areas of focus or where strategic partnership makes more sense for our business," said Andrew Plump, M.D., Ph.D., Chief Medical and Scientific Officer of Takeda. "The formation of Myovant Sciences represents such an innovative partnership arrangement to further advance relugolix by relying on Roivant's and Myovant's in-house development capabilities in the major markets where they are building deep expertise, while leveraging Takeda's commercial presence in certain Asian territories."

"We are very pleased to partner with Takeda to meet the needs of patients suffering from hormone-driven diseases and disorders," said Vivek Ramaswamy, CEO of Roivant Sciences, Inc. "The creation of Myovant enables a 'win-win' outcome for both our partner and for patients by launching a company to address major unmet medical needs in women's health, prostate cancer and beyond."

Appointment of Dr. Lynn Seely as President & Chief Executive Officer

Lynn Seely, MD, brings over 20 years of drug development and biopharmaceutical company leadership to her role as the President & Chief Executive Officer of Myovant Sciences, Inc. Most recently, Dr. Seely served as Chief Medical Officer of Medivation, Inc. from its early stages in March 2005 through October 2015. She served on the Executive Committee and led the development of XTANDI for the treatment of metastatic castration-resistant prostate cancer from IND-enabling studies through to NDA approval and post-approval clinical studies. Dr. Seely was responsible for building the clinical organization at Medivation, as well as the regulatory, quality, project management, medical affairs and biologics manufacturing functions. Dr. Seely currently serves on the board of directors of Blueprint Medicines Corporation, and she previously served as Vice President of Clinical Development at Anesiva, Inc. (formerly Corgentech) and at Cytyc Health Corporation. Dr. Seely received a medical degree from the University of Oklahoma College of Medicine and completed her residency in internal medicine at Yale-New Haven Hospital. After serving as Chief Resident in Internal Medicine at Yale University School of Medicine, she completed her basic science and clinical fellowship in endocrinology and metabolism at the University of California, San Diego.

"I look forward to delivering on Myovant's mission to bring innovative new treatments to women suffering from diseases such as uterine fibroids and endometriosis and to men with prostate cancer," stated Dr. Lynn Seely, President & CEO of Myovant Sciences, Inc. "Relugolix and our partnership with Takeda represent an exceptional foundation on which to build this exciting new company."

About Relugolix

Relugolix is a once-daily, orally administered, potential best-in-class gonadotropin-releasing hormone (GnRH) receptor antagonist for the treatment of uterine fibroids and endometriosis, and a potential best- and first-in-class treatment for hormone-sensitive prostate cancer (HSPC). Relugolix has been evaluated in over 1,300 patients to date, and has successfully demonstrated significant clinical benefit and was generally well-tolerated across multiple, large, randomized phase 2 clinical trials in three different indications. Takeda is currently enrolling two phase 3 clinical trials of relugolix for registration in Japan for the treatment of uterine fibroids.

By inhibiting GnRH receptors in the pituitary gland, relugolix rapidly reduces circulating sex hormone levels leading to suppression of estrogen and testosterone. Suppression of these sex hormones improves the symptoms of women with uterine fibroids and endometriosis, and decreases prostate-specific antigen (PSA) levels in men with HSPC.

In a 216-patient phase 2 study for the treatment of uterine fibroids, women who received relugolix had a significant reduction in menorrhagia, or abnormally heavy bleeding during menstruation. In a 487-patient phase 2 study for the treatment of endometriosis, women who received relugolix had a significant reduction in both non-menstrual and menstrual pelvic pain. Based on these results, two phase 3 registration studies in women with uterine fibroids are underway in Japan(NCT02655237, NCT02655224). In two phase 2 studies in approximately 225 men with HSPC, which included control arms of either an injectable GnRH agonist (leuprolide acetate) or a GnRH antagonist (degarelix), respectively, oral once-daily relugolix suppressed serum testosterone to castrate levels and decreased PSA. The safety of relugolix across all phase 2 studies was generally well-tolerated, consistent with the mechanism of action.

The clinical experience to date, supported by an extensive preclinical development program, suggests that oral relugolix, administered once-daily, could be an important advancement in the treatment options available for women suffering from endometriosis and uterine fibroids. In addition, relugolix could provide men with HSPC an important new treatment option as the first oral GnRH receptor antagonist that offers an alternative to injectable therapies.

About RVT-602

RVT-602 (TAK-448) is a kisspeptin analog that acts to stimulate the physiologic release of GnRH and downstream hormones important in fertility such as luteinizing hormone. Recent evidence from trials performed in women undergoing In-vitro Fertilization (IVF) revealed that the native kisspeptin peptide has the potential to act as an alternative to human chorionic gonadotropin (hCG) or GnRH agonists in triggering egg maturation, an essential step in every IVF cycle.

About Myovant Sciences

Myovant Sciences is focused on innovative treatments for women's health conditions and prostate cancer. The company's lead program is relugolix, a phase 3 drug candidate for multiple indications, including uterine fibroids, endometriosis and prostate cancer. Myovant was formed through a strategic partnership between Roivant Sciences and Takeda. Additional information about Myovant Sciences is available through its website, www.myovant.com.

About Roivant Sciences

Roivant Sciences delivers R&D solutions to its partners in the biopharmaceutical industry, helping them unlock value from their pipelines by completing the clinical development of promising drug candidates. Roivant is an integrated biopharmaceutical company with world-class drug development experts working across multiple clinical and functional areas. The company allows pharmaceutical companies to realize the full potential of their research while improving the lives of patients and their families. Additional information about Roivant Sciences is available through its website, www.roivant.com.

About Takeda
Takeda Pharmaceutical Company Limited (TSE: 4502) is a global, R&D-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its research efforts on oncology, gastroenterology and central nervous system therapeutic areas. It also has specific development programs in specialty cardiovascular diseases as well as late-stage candidates for vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology, central nervous system and gastroenterology, as well as its presence in emerging markets, fuel the growth of Takeda. More than 30,000 Takeda employees are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit http://www.takeda.com/news.

Takeda's Forward-Looking Statements

This press release contains "forward-looking statements." Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future, future revenues and profitability from or growth or any assumptions underlying any of the foregoing. Statements made in the future tense, and words such as "anticipate," "expect," "project," "continue," "believe," "plan," "estimate," "pro forma," "intend," "potential," "target," "forecast," "guidance," "outlook," "seek," "assume," "will," "may," "should," and similar expressions are intended to qualify as forward-looking statements. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to: required regulatory approvals for the transaction may not be obtained in a timely manner, if at all; the conditions to closing of the transaction may not be satisfied; competitive pressures and developments; applicable laws and regulations; the success or failure of product development programs; actions of regulatory authorities and the timing thereof; changes in exchange rates; and claims or concerns regarding the safety or efficacy of marketed products or product candidates in development.

The forward-looking statements contained in this press release speak only as of the date of this press release, and neither Roivant Sciences Ltd., Roivant Sciences, Inc., Myovant Sciences Ltd., Myovant Sciences, Inc., nor Takeda undertakes any obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If one or more of these statements is updated or corrected, investors and others should not conclude that additional updates or corrections will be made.

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