Myovant Sciences Announces Positive Top-line Results from Takeda's Phase 3 Study Evaluating the Efficacy and Safety of Relugolix Compared with Leuprorelin for the Treatment of Uterine Fibroids

October 2, 2017

-- Relugolix meets primary endpoint, achieving 82.2% response rate and demonstrating non-inferiority to leuprorelin

BASEL, Switzerland, Oct. 2, 2017 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV) today announced that Takeda Pharmaceutical Company Limited ("Takeda") has reported positive top-line results from a Phase 3 study evaluating the efficacy and safety of relugolix compared with leuprorelin for the treatment of uterine fibroids in Japanese women. Relugolix was statistically non-inferior to leuprorelin (p = 0.0013) meeting the study's primary endpoint, the proportion of patients achieving a pre-defined reduction in menstrual bleeding.

Myovant is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health and endocrine diseases with relugolix as its lead product candidate. Relugolix, an oral gonadotropin-releasing hormone (GnRH) receptor antagonist, rapidly lowers estrogen and progesterone in women when administered orally once-daily. The incidence of adverse events in the Phase 3 study was generally similar between treatment groups and consistent with the mechanism of action of the study medications.

"The positive results of decreased menstrual bleeding from Takeda's Phase 3 study of relugolix in Japanese women with uterine fibroids provides strong support for Myovant's ongoing Phase 3 studies with relugolix in North America, Europe and other regions," stated Lynn Seely, M.D., President and Chief Executive Officer of Myovant Sciences. "Uterine fibroids result in debilitating heavy menstrual bleeding and anemia in millions of women throughout the world, oftentimes requiring a hysterectomy to control the bleeding. Myovant is working to develop relugolix, an oral, once-daily medication that can potentially provide women with an alternative option to major surgery for the treatment of uterine fibroids."

Takeda Phase 3 Study Design and Results

The Phase 3 trial was a multicenter, randomized, double-blind non-inferiority study conducted in Japan to evaluate the efficacy and safety of relugolix in approximately 280 women with heavy menstrual bleeding associated with uterine fibroids. Patients were randomized 1:1 to receive either relugolix 40 mg, administered orally once daily, or leuprorelin, administered by subcutaneous injection every four weeks, at a dose of 1.88 mg or 3.75 mg, for 24 weeks. Leuprorelin, or leuprolide acetate, is an injectable GnRH agonist approved for pre-operative treatment of uterine fibroids in Japan.

The primary endpoint was the proportion of women who achieved a total score of less than 10 on the Pictorial Blood Loss Assessment Chart, or PBAC, a patient-reported outcome measure for evaluation of menstrual blood loss in clinical trials, from week 6 to week 12. All participants had a PBAC ≥ 120 upon entry into the study. In the study, relugolix successfully demonstrated non-inferiority to leuprorelin with 82.2% of patients treated with relugolix achieving a score of less than 10 on the PBAC, compared with 83.1% of patients treated with leuprorelin (p = 0.0013). The incidence of adverse events in the Phase 3 study was generally similar between treatment groups and consistent with the mechanism of action of the study medications.

Takeda is conducting a second Phase 3 trial evaluating relugolix in approximately 70 Japanese women who have pain associated with uterine fibroids and anticipates preliminary top-line data in the fourth quarter of 2017. Takeda plans to submit the data from both studies to regulatory authorities in Japan for marketing authorization of relugolix for the treatment of uterine fibroids.

Myovant Phase 3 Program for Uterine Fibroids

Myovant is currently conducting a Phase 3 clinical program consisting of two international, replicate pivotal clinical trials (LIBERTY 1 and LIBERTY 2), initiated in January 2017, of relugolix in women with heavy menstrual bleeding associated with uterine fibroids. Women with heavy menstrual bleeding associated with uterine fibroids in the LIBERTY 1 and LIBERTY 2 trials are randomized in a 1:1:1 ratio to one of three arms. Women receive treatment with relugolix 40 mg once daily co-administered with commercially available low-dose hormonal add-back therapy for 24 weeks, relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. Approximately 390 women are targeted to be enrolled in each of the two replicate LIBERTY 1 and LIBERTY 2 trials, with 130 women in each of the two active treatment arms and 130 women in the placebo arm. To be enrolled, women must have a monthly menstrual blood loss of at least 80 mL, measured by the alkaline hematin method, a quantitative measure of menstrual blood loss.

The primary efficacy endpoint for LIBERTY 1 and LIBERTY 2 is the proportion of all women enrolled who achieve a menstrual blood loss volume of less than 80 mL and at least a 50% reduction in menstrual blood loss volume from baseline over the last month of treatment as measured by the alkaline hematin method. The secondary efficacy endpoints include measures of change from baseline in hemoglobin, assessment of the impact of therapy on quality-of-life measures, the reduction in uterine and fibroid volume, and pain reduction. Safety, including bone mineral density changes as measured by dual-energy x-ray absorptiometry, is also being assessed.

Eligible women completing the LIBERTY 1 or LIBERTY 2 trial will be offered the opportunity to enroll in an active treatment extension study where all

patients will receive relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 28-week period, for a total treatment period of 52 weeks, to evaluate the safety and durability of efficacy of long-term treatment.

Myovant is solely responsible for obtaining Food and Drug Administration (FDA) approval for relugolix in the United States. While the trial design and endpoints of the Takeda Phase 3 study differ from those in the Phase 3 studies Myovant is currently conducting, the data from the Takeda study are expected to be used to support Myovant's New Drug Application (NDA) for relugolix in the United States and other geographic regions.

About Relugolix

Relugolix is an oral, once-daily, small molecule GnRH receptor antagonist that has been evaluated in almost 1,600 study participants in Phase 1, Phase 2 and Phase 3 clinical trials. In these trials, relugolix has been shown to be generally well tolerated and to suppress estrogen and progesterone levels in women and testosterone levels in men. Common side effects are consistent with suppression of these hormones. In the ongoing Phase 3 SPIRIT clinical trials in women with endometriosis-associated pain and the ongoing Phase 3 LIBERTY clinical trials in women with heavy menstrual bleeding associated with uterine fibroids, relugolix will be evaluated with and without low-dose hormonal add-back therapy, the addition of which is expected to decrease potential side effects such as bone mineral density loss and hot flashes. The ongoing Phase 3 HERO study is evaluating relugolix in men with advanced prostate cancer.

About Uterine Fibroids

Uterine fibroids are noncancerous tumors composed of smooth muscle and fibrous connective tissue that develop in or on the walls of the uterus. In addition to an individual's genetic predisposition, estrogens are well known to play an important role in the regulation of fibroid growth. Although uterine fibroids are benign tumors that are often asymptomatic, they can cause debilitating symptoms such as abnormal uterine bleeding, heavy or painful periods, anemia, abdominal pain, backache, increased abdominal girth and bloating, urinary frequency or retention, constipation or painful defecation, pregnancy loss, painful intercourse and, in some cases, infertility. These symptoms can also lead to loss of productivity at work, limitations in normal activities of daily living, and social embarrassment. Uterine fibroids are among the most common reproductive tract tumors in women. It is estimated that approximately 5 million women in the United States suffer from symptoms of uterine fibroids, approximately 3 million of whom are inadequately treated by current medical therapy and require further treatment.

About Myovant Sciences

Myovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health and endocrine diseases. Myovant's lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a GnRH receptor antagonist. Myovant has initiated three clinical programs for relugolix consisting of five international Phase 3 clinical trials, two in women with heavy menstrual bleeding associated with uterine fibroids (LIBERTY 1 & 2), two in women with endometriosis-associated pain (SPIRIT 1 & 2), and one in men with advanced prostate cancer (HERO). Myovant is simultaneously developing MVT- 602, a kisspeptin agonist, for the treatment of female infertility as part of assisted reproduction. Takeda Pharmaceuticals International AG has granted Myovant an exclusive, worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries where Takeda retains exclusive rights) and an exclusive license to develop and commercialize MVT-602 in all countries worldwide. Over time, the company intends to expand its development pipeline to include other potential treatments for women's health and endocrine diseases. For more information, please visit the company's website at www.myovant.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Myovant's plans for the development of its pipeline and completion of its clinical studies. Forward-looking statements can be identified by the words "believe," "anticipate," "continue," "estimate," "project," "expect," "plan," "potential," "intends," "will," "would," "could," "should" or the negative or plural of these words or other similar expressions that are predictions or indicate future events, trends or prospects. 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 our product development activities and clinical trials, increased regulatory requirements, and interim results or other preliminary analyses do not ensure that later or final results in a clinical trial or in related or similar clinical trials will replicate those interim results. There can be no assurance that any of our product candidates will ever receive regulatory approval or be successfully commercialized.

For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Myovant's business in general, see the "Risk Factors" section of our quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 10, 2017, and other filings that Myovant makes with the SEC from time to time. These forward-looking statements are based on information available to Myovant as of the date of this press release and speak only as of the date of this release. Myovant disclaims any obligation to update these forward-looking statements, except as may be required by law.

Contacts:
Investors
DeDe Sheel
Director, Investor Relations
Myovant Sciences, Inc.
650.457.1679

Media
Julie Normart
Pure Communications
jnormart@purecommunications.com
415.946.1087

300529551.html

SOURCE Myovant Sciences