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

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-- Relugolix met the primary endpoint with 57.6% of women achieving marked improvement in pain symptoms compared to 3.1% of women receiving placebo ($p < 0.0001$) --

BASEL, Switzerland, Nov. 9, 2017 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV), a clinical-stage biopharmaceutical company focused on women's health and endocrine diseases, 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 for the treatment of pain associated with uterine fibroids. Relugolix, an oral once-daily gonadotropin-releasing hormone (GnRH) receptor antagonist that rapidly lowers estrogen and progesterone in women, is also being evaluated by Myovant in a Phase 3 clinical program consisting of two international, replicate pivotal clinical trials (LIBERTY 1 and LIBERTY 2) of relugolix in women with heavy menstrual bleeding associated with uterine fibroids.

Takeda's Phase 3 trial primary endpoint was met with 57.6% of women with uterine fibroids treated with relugolix demonstrating a marked improvement in pain symptoms (maximum pain score of ≤ 1 on a scale of 0 to 10) compared with 3.1% of women treated with placebo ($p < 0.0001$). Adverse events in patients treated with relugolix were consistent with the mechanism of action and adverse events observed in previous studies.

"Two Phase 3 studies of relugolix conducted by Takeda have now demonstrated significant benefit on the two most debilitating symptoms suffered by women with uterine fibroids," stated Juan Camilo Arjona Ferreira, M.D., Chief Medical Officer of Myovant Sciences. "Treatment with relugolix significantly decreased heavy menstrual bleeding and now pain associated with uterine fibroids, with the majority of women in the current study experiencing little or no pain by the end of the 12-week study."

Takeda's Phase 3 Program for Uterine Fibroids

This Phase 3 study was a multicenter, randomized, double-blind placebo-controlled study conducted in Japan to evaluate the efficacy and safety of relugolix in the treatment of pain symptoms associated with uterine fibroids compared to placebo. Sixty-five patients were randomized 1:1 to receive either relugolix 40 mg, administered orally once daily, or placebo for 12 weeks.

The primary endpoint was the proportion of women who achieved a maximum score of 1 or less on the Numerical Rating Scale (NRS) for pain associated with uterine fibroids during each of the 28 days before the final dose. The NRS is a self-reported instrument assessing pain on an 11-point scale as follows: 0 (no pain), 1-3 (mild pain), 4-6 (moderate pain), and 7-10 (severe pain). All participants had a maximum NRS ≥ 4 upon entry into the study and completed the scale each day using a diary while on the study. Of the women treated with relugolix, 57.6% achieved the primary endpoint compared to 3.1% in the placebo arm ($p < 0.0001$). Common adverse events (≥10%) reported more frequently in patients treated with relugolix relative to patients treated with placebo included hot flush, metrorrhagia, hyperhidrosis and menorrhagia, which are consistent with the mechanism of action and adverse events observed in previous studies.

On October 2, 2017, Myovant announced positive top-line results from Takeda's first Phase 3 study evaluating the efficacy and safety of relugolix compared to leuprorelin for the treatment of heavy menstrual bleeding and uterine fibroids. In that study, relugolix successfully demonstrated non-inferiority to leuprorelin, with 82.2% of patients treated with relugolix meeting the study's primary endpoint, which was the proportion of patients achieving a pre-defined marked reduction in menstrual bleeding, compared with 83.1% of patients treated with leuprorelin ($p = 0.0013$). The incidence of adverse events was generally similar between treatment groups and consistent with the mechanism of action of the study medications.

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's 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) of relugolix in women with heavy menstrual bleeding associated with uterine fibroids. In these studies, women are randomized in a 1:1:1 ratio to one of three arms to 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 Takeda's Phase 3 studies differ from those in the Phase 3 studies Myovant is currently conducting, the data from the Takeda studies 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 over 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.

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