Myovant Sciences Announces Presentation of Positive Phase 2 Data for Relugolix in Women with Heavy Menstrual Bleeding and Uterine Fibroids at the Annual Meeting of the American Congress of Obstetricians and Gynecologists

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--Relugolix demonstrates statistically significant difference compared with placebo on primary endpoint ($p < 0.0003$)--Myovant Sciences is conducting two phase 3 studies evaluating relugolix in women with uterine fibroids

BASEL, Switzerland, May 7, 2017 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV) today announced the presentation of data from a placebo-controlled Phase 2 dose-finding study conducted by Takeda Pharmaceutical Company Ltd. in Japan evaluating the ability of relugolix to decrease heavy menstrual bleeding in women with uterine fibroids. The study met its primary endpoint with relugolix demonstrating a marked decrease in menstrual blood loss from Week 6 to Week 12 as assessed by a patient-reported outcome ($p < 0.0003$ at relugolix 40-mg dose vs. placebo). The findings were presented during a poster session (Abstract #17H) on May 7 at the 2017 Annual Clinical and Scientific Meeting of the American Congress of Obstetricians and Gynecologists, which is being held in San Diego, California, May 6-9, 2017.

Phase 2 Study Results

Relugolix demonstrated statistical significance over placebo in the primary endpoint of the proportion of subjects who had reduction in menstrual blood loss from a score of at least 120 required at study entry to less than 10 from Week 6 through Week 12 on the Pictorial Blood Loss Assessment Chart (PBAC). Relugolix decreased menstrual blood loss in a dose-dependent manner with the highest proportion of responses [84%, 95% confidence interval (74% to 93%) vs. placebo] in the relugolix 40-mg group.

In the relugolix 40-mg group, 73% of women achieved amenorrhea (i.e. a PBAC score of 0, representing no menstrual blood loss) from Week 6 through Week 12. No women in the placebo group achieved amenorrhea. At Week 12, the 40-mg group demonstrated an absolute reduction in myoma and uterine volumes of approximately 50% from baseline compared to placebo. By Week 12, there was an increase in hemoglobin levels in the relugolix 20- and 40-mg groups compared to placebo. Patient-reported pain from uterine fibroids, based upon the numerical rating scale (NRS) score, indicated that patients who received relugolix treatment had fewer pain symptoms from Week 6 to Week 12, with the relugolix 40-mg dose having the greatest reported reduction of pain symptoms.

The most commonly observed adverse events (occurring more than 10% more frequently in treatment groups vs. placebo) were mild or moderate in severity and included headache, metrorrhagia, menorrhagia, and hot flush. Bone mineral density decreased in a dose-dependent fashion with the greatest loss (-2.3%) observed in the relugolix 40-mg group.

"These data provide a strong basis for our ongoing phase 3 studies, LIBERTY 1 & 2, which are evaluating relugolix co-administered with low-dose hormonal add-back therapy in women with uterine fibroids and heavy menstrual bleeding," said Lynn Seely, MD, President & Chief Executive Officer of Myovant Sciences. "Myovant hopes to provide women with a well-tolerated medical therapy to treat symptoms of uterine fibroids as an alternative to hysterectomy and other invasive procedures commonly performed to treat this condition."

Phase 2 Study Design

The Phase 2 multicenter, randomized, double-blind, parallel-group, placebo-controlled study conducted by Takeda Pharmaceutical Company was designed to evaluate the safety and efficacy of relugolix administered orally at a dose of 10, 20, or 40 mg once daily for 12 weeks in premenopausal Japanese women, 20 years of age or older, with a diagnosis of uterine fibroids confirmed by imaging or laparoscopy and heavy menstrual bleeding attributed to uterine fibroids (N = 216). Heavy menstrual bleeding was defined as a score on the PBAC of at least 120, which corresponds to a blood loss of approximately 80 mL.

The study consisted of a 4- to 12-week pretreatment period with a placebo run-in period that was initiated during the first menstrual cycle; after completion of the pretreatment period patients were randomly assigned to either a relugolix treatment group or placebo for a 12-week treatment period and a 4-week follow-up period. The primary outcome measure was the proportion of patients with a total PBAC score of less than 10 from Week 6 to Week 12. Secondary endpoints included the proportion of patients with amenorrhea (PBAC score of 0), changes in myoma and uterine volumes, change in hemoglobin, pain symptoms assessed by the NRS score, and quality of life symptom severity score assessed by the UFS-QOL score.

About Relugolix

Relugolix is an oral, once-daily, small molecule that acts as a gonadotropin-releasing hormone (GnRH) receptor antagonist and has been evaluated in over 1,300 study participants in Phase 1 and multiple large controlled Phase 2 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 the lowering of estrogen and progesterone in women and testosterone in men.

Myovant Sciences has an exclusive, worldwide license (excluding Japan and certain other Asian countries) to develop and commercialize relugolix. Myovant is developing relugolix as an oral, once-daily, potential best-in-class GnRH receptor antagonist for uterine fibroids, endometriosis, and prostate cancer.

LIBERTY 1 and LIBERTY 2 are double-blind, placebo-controlled Phase 3 international clinical trials in women with heavy menstrual bleeding associated with uterine fibroids, evaluating relugolix with and without low-dose hormonal add-back therapy. Each trial is expected to enroll approximately 390 women with a diagnosis of uterine fibroids confirmed by ultrasound and heavy menstrual bleeding. Eligible women will be randomized to one of three groups: relugolix 40 mg orally once daily co-administered with low-dose hormonal add-back therapy (1 mg estradiol/0.5 mg norethindrone acetate) for 24 weeks, relugolix 40 mg orally 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. Eligible patients completing the initial 24-week blinded assessment will be offered an active treatment extension for an additional 24-week period.

About Uterine Fibroids

Uterine fibroids are non-cancerous 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 and progesterone play important roles 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 menstrual 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. Uterine fibroids are among the most common benign reproductive tract tumors in women. It is estimated that approximately 5 million women in the United States alone suffer from symptomatic uterine fibroids.

About Myovant Sciences

Myovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health and other endocrine-related disorders. Myovant's lead product candidate is relugolix, an oral, once-daily small molecule that acts as a GnRH receptor antagonist. Myovant has initiated a Phase 3 clinical program, LIBERTY, for relugolix in women with uterine fibroids as well as a Phase 3 clinical program, HERO, for relugolix in men with advanced prostate cancer, and plans to initiate an additional Phase 3 clinical program for relugolix in women with endometriosis-associated pain in the second quarter of 2017. Myovant is simultaneously developing MVT-602, an analog of kisspeptin, for the treatment of female infertility as part of assisted reproduction. Over time the company intends to expand its development pipeline to include other potential treatments for women's health and endocrine-related disorders. For more information, please visit the company's website at myovant.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Myovant's plans to advance the clinical development of its product candidates and expand its development pipeline. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with the success, cost, and timing of the company's product development activities and clinical trials. For further information regarding risks and uncertainties that could cause actual results to differ from those anticipated by these forward-looking statements, as well as risks relating to Myovant's business in general, see the "Risk Factors" section of Myovant's quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on February 13, 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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