Myovant Sciences Announces Presentation of Positive Phase 2 Data for Relugolix in Women with Endometriosis-Associated Pain at the World Congress on Endometriosis

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-- Relugolix demonstrates statistically significant reduction in pelvic pain compared with placebo on primary endpoint (p < 0.0001)-- Myovant Sciences will evaluate relugolix in women with endometriosis in upcoming Phase 3 program

BASEL, Switzerland, May 19, 2017 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV) today announced the presentation of data from a placebo-controlled Phase 2 study conducted by Takeda Pharmaceutical Company Ltd. ("Takeda") evaluating relugolix in Japanese women with endometriosis-associated pain. The study met its primary endpoint with relugolix, an oral once-daily hormonal treatment, resulting in a statistically significant reduction in overall pelvic pain compared with placebo. The findings were presented during an oral presentation on May 19 at the 2017 World Congress on Endometriosis in Vancouver, Canada.

Phase 2 Study Results

Relugolix demonstrated statistically significant dose-dependent reductions over placebo in each of three study arms (10, 20, and 40 mg) on the primary endpoint of change from baseline in overall pelvic pain at the end of the 12-week treatment period. Overall pelvic pain was assessed using a 100 millimeter (mm) Visual Analogue Scale (VAS) in which 0 mm indicated "No pain" and 100 mm indicated "Pain as bad as you can imagine." Scores were reported daily in patient diaries.

Reductions in pain symptoms were dose dependent, with the greatest decline in overall pelvic pain seen in the relugolix 40-mg group (p < 0.0001 vs. placebo). The mean reduction from baseline in overall pelvic pain for the relugolix 40-mg group at the end of the treatment period was -10.4 mm, representing a -72.9% mean change from baseline pain at the beginning of the study. The mean reduction in the placebo arm of -3.8 mm represented an -8.6% mean change from baseline. The reduction achieved by relugolix, 40 mg orally once daily, was comparable to that observed in a reference arm of patients receiving monthly injections of leuprorelin.

For pain during menses, or dysmenorrhea, the relugolix 40-mg group achieved a mean reduction from baseline of -29.7 mm (-97.1% mean change from baseline) compared with -5.2 mm (-11.7% mean change from baseline) in the placebo group. No clear trend of change in dyspareunia, or painful sexual intercourse, was observed in the small subset of patients who reported sexual activity in the study.

Patients in each relugolix group demonstrated greater reductions from baseline in the use of analgesics and greater improvement from baseline on each subcategory of the long-form 30-item Endometriosis Health Profile (EHP-30) scale measuring quality of life and symptom severity than did patients in the placebo group.

The most commonly observed adverse events (occurring in at least 10% of patients in the relugolix groups and greater in the relugolix than placebo groups) were primarily mild or moderate in severity and included irregular or heavy menstrual bleeding (metrorrhagia, menorrhagia, irregular menstruation), sweating (hyperhidrosis), and hot flush. Bone mineral density decreased in a dose-dependent fashion in the relugolix groups with the greatest losses (mean percent change from baseline) observed in the relugolix 40-mg group (-2.1%), as compared with the placebo group (-0.1%) and the leuprorelin group (-2.2%).

"The pain associated with endometriosis is often inadequately treated and adversely affects the lives of too many women. The data presented today provide a compelling rationale for our upcoming Phase 3 studies evaluating relugolix co-administered with low-dose hormonal add-back therapy in women with endometriosis-associated pain," said Lynn Seely, MD, President & Chief Executive Officer of Myovant Sciences. "Myovant hopes to provide a well-tolerated, once-daily oral therapy for women who suffer from the symptoms of endometriosis."

Phase 2 Study Design

The Phase 2 multicenter, randomized, double-blind, parallel-group, placebo-controlled study conducted by Takeda 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 both endometriosis and moderate-to-severe dysmenorrhea or pelvic pain (N = 487 patients). The study also included an active reference group that received monthly injections of leuprorelin.

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, an injectable leuprorelin group, or placebo for a 12-week treatment period. Upon completion of the 12-week treatment period, eligible participants could enter a 12-week extension study.

The primary outcome measure was the change from baseline in mean VAS score for overall pelvic pain at the end of the treatment period. Secondary endpoints included VAS scores for pelvic pain, dysmenorrhea, and dyspareunia during the treatment period, physician Biberoglu & Behrman (B & B)

scores and modified patient B & B scores for pelvic pain and dyspareunia, use of analgesics during the treatment period, decrease in menstrual blood loss and achievement of amenorrhea, and quality of life and symptom severity as assessed by long-form 30-item EHP-30 scores.

About Relugolix

Relugolix is an oral, once-daily, small molecule 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 was generally well tolerated and suppressed estrogen and progesterone levels in women and testosterone levels in men. Common side effects of relugolix are consistent with its mechanism of action in lowering these sex hormones.

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, GnRH receptor antagonist for heavy menstrual bleeding associated with uterine fibroids, endometriosis-associated pain, and advanced prostate cancer.

About Endometriosis

Endometriosis is a disease in which tissue that normally lines the uterus is found outside the uterine cavity, commonly in the lower abdomen or pelvis, on ovaries, the bladder, and the colon. This tissue outside the uterus results in chronic inflammation and can cause scarring and adhesions. The symptoms associated with endometriosis include painful periods and chronic pelvic pain, painful ovulation, pain during or after sexual intercourse, heavy bleeding, fatigue, and infertility. Endometriosis can also impact general physical, mental, and social well-being. For endometriosis-associated pain, initial treatment options include oral contraceptives and over-the-counter pain medications. In more severe cases, GnRH agonists such as leuprorelin are used for short-term treatment. It is estimated that approximately 6 million women in the United States suffer from symptomatic endometriosis, 1.2 million of whom are inadequately treated by oral contraceptives and require additional 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 GnRH receptor antagonist. Myovant has initiated a Phase 3 clinical program, consisting of two international clinical trials, LIBERTY 1 and LIBERTY 2, for relugolix in women with heavy menstrual bleeding associated with uterine fibroids, as well as a Phase 3 clinical program, HERO, for relugolix in men with advanced prostate cancer. Myovant 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 diseases. 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.

Media Contact:
Julie Normart
Pure Communications
jnormart@purecommunications.com
415.946.1087