Myovant Sciences Announces Presentation of Data at the European Congress of Endocrinology from Phase 2 Extension Study Evaluating Relugolix in Women with Endometriosis-Associated Pain

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-- Treatment with relugolix for 24 weeks was generally well tolerated in women with endometriosis-associated pain, with a safety profile that is consistent with its mechanism of action-- Relugolix treatment up to 40 mg orally once daily for 24 weeks resulted in dose-dependent reductions in overall pelvic pain, dysmenorrhea, and non-menstrual pelvic pain compared with placebo-- Myovant Sciences will evaluate relugolix in women with endometriosis in upcoming Phase 3 program

BASEL, Switzerland, May 24, 2017 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV) today announced the presentation of data from a Phase 2 extension study conducted by Takeda Pharmaceutical Company Ltd. ("Takeda") evaluating relugolix in Japanese women with endometriosis-associated pain. Oral, once-daily treatment with relugolix (10, 20, or 40 mg) was generally well tolerated during the 24 weeks comprising the initial 12-week study and the 12-week extension study. Treatment-emergent adverse events for patients receiving relugolix, such as hot flush and menorrhagia, were consistent with the drug's mechanism of action.

Efficacy outcomes for the full 24-week period were consistent with outcomes during the initial 12-week trial, with greater dose-dependent reductions in overall pelvic pain, dysmenorrhea, and non-menstrual pelvic pain seen in the relugolix treatment arms compared to placebo. The largest decrease was seen in the relugolix 40-mg group throughout the treatment period, and the reductions in the mean Visual Analogue Scale (VAS) score from baseline for overall pelvic pain, dysmenorrhea, and non-menstrual pelvic pain in the relugolix 40-mg group were similar to those in an active reference group receiving monthly injections of leuprorelin. The findings were presented during a poster presentation on May 23 at the 2017 European Congress of Endocrinology in Lisbon, Portugal.

Long-Term Extension Study Results

Of the 484 patients randomized and administered study drug in the initial 12-week study, 397 (82%) were enrolled in the extension study, and 373 (94% of enrolled patients) completed the treatment period for the extension study. There were no clinically relevant differences in the demographic and baseline characteristics of the treatment groups.

The incidence of mild and moderate adverse events in the relugolix 20- and 40-mg groups was higher than that observed in the placebo group, and comparable to that observed in an active reference group receiving monthly injections of leuprorelin. 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 time- and dose-dependent fashion in the relugolix groups with the greatest losses (mean percent change from baseline) after 24 weeks observed in the relugolix 40-mg group (-4.9%), as compared with the placebo group (-0.2%) and the leuprorelin group (-4.4%). The menstruation recovery period was 21 to 37 days after the last dose in the relugolix groups; the recovery period in the leuprorelin group was 73 days.

Reductions in mean VAS score from baseline for overall pelvic pain, dysmenorrhea, and non-menstrual pelvic pain in the relugolix groups were dose-dependent, with the largest decreases in the relugolix 40-mg group throughout the treatment period. Pain intensity was assessed using a 100 millimeter (mm) 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.

The mean reduction in overall pelvic pain for the relugolix 40-mg group at the end of the extension study was -11.9 mm from baseline (15.3 mm), compared to a mean reduction of -3.2 mm in the placebo arm from baseline (15.6 mm). The reduction achieved by relugolix, 40 mg orally once daily, was comparable to that observed in the active control arm of patients receiving monthly injections of leuprorelin.

For pain during menses, or dysmenorrhea, the relugolix 40-mg group achieved a mean reduction of -29.5 mm at the end of extension study from baseline (30.4 mm) compared to a mean reduction of -5.8 mm in the placebo group from baseline (28.4 mm). No clear trend was observed in mean VAS scores from baseline across the dosing groups for dyspareunia with a trend for lower scores over time for the relugolix 40 mg and leuprorelin groups.

The proportion of patients reporting no pain in the VAS score for overall pelvic pain at the end of the treatment period were 0% for placebo, 7% for relugolix 10 mg, 20% for relugolix 20 mg, 50% for relugolix 40 mg, and 57% for leuprorelin.

"The findings in the long-term extension study offer additional support 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. "We look forward to initiating those studies and advancing the development of relugolix in the months to come."

Long-Term Extension Study Design

The Phase 2 multicenter, randomized, parallel-group, placebo-controlled long-term extension 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 a full 24 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 who participated in a prior double-blind, 12-week study. The study also included an active reference group that received monthly injections of leuprorelin.

The prior Phase 2 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 that treatment period, eligible participants were offered the opportunity to enter the 12-week extension study. Patients in the extension study were assigned to the same treatment groups as the preceding Phase 2 study.

The study's primary outcome was assessment of safety, including bone mineral density, adverse events, vital signs, weight, 12-lead electrocardiograms, and clinical laboratory tests. The secondary endpoint was an assessment of efficacy through 24 weeks including VAS scores for overall pelvic pain, dysmenorrhea, and dyspareunia at the end of treatment. Additional endpoints included endometriosis-associated pain symptoms assessed by physician Biberoglu & Behrman (B & B) scores and modified patient B & B scores, use of analgesics during the treatment period, decrease in menstrual blood loss and achievement of amenorrheic state, 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.

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