



## Myovant Sciences Presents Additional Data on Relugolix Combination Therapy from Studies in Endometriosis and Uterine Fibroids

October 21, 2020

- Seven oral and poster presentations presented at the American Society for Reproductive Medicine (ASRM) 2020 Virtual Congress
- Oral presentation on efficacy and safety data from Phase 3 SPIRIT program selected as the best clinical abstract in endometriosis
- Oral presentation on efficacy and safety data from the LIBERTY long-term extension study in uterine fibroids selected as a prize paper

BASEL, Switzerland, Oct. 21, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced the presentation of data from clinical studies of its once-daily relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with endometriosis and in women with uterine fibroids. The data were presented in virtual oral and poster sessions during the [American Society for Reproductive Medicine \(ASRM\) 2020 Virtual Congress](#), held October 17-21, 2020.

"For millions of women, the symptoms of endometriosis and uterine fibroids, such as pain and heavy menstrual bleeding, can be highly debilitating and have a significant impact on their daily lives," said Juan Camilo Arjona Ferreira, M.D., chief medical officer of Myovant Sciences. "These additional data further support our vision for a one pill, once-a-day treatment that provides symptom relief with minimal side effects, potentially allowing for long-term treatment of women suffering from these common chronic conditions."

### Details of the presentations from studies of women with endometriosis are as follows:

The Phase 3 SPIRIT program evaluated the efficacy and safety of once-daily relugolix combination therapy in women with endometriosis. The SPIRIT 1 and 2 studies achieved their co-primary endpoints, demonstrating clinically meaningful reductions in dysmenorrhea (menstrual pain) and non-menstrual pelvic pain.

- **Efficacy and Safety of Relugolix Combination Therapy in Women with Endometriosis-Associated Pain: Phase 3 Randomized, Double-Blind, Placebo-Controlled Study (SPIRIT 1 and 2)** (oral presentation, O-187, Endometriosis Special Interest Group Prize Paper [Best in Clinical/Population Science])

In the SPIRIT 1 and 2 studies, relugolix combination therapy resulted in a clinically meaningful reduction in dysmenorrhea (74.5% vs. 26.9% and 75.2% vs. 30.4% for SPIRIT 1 and 2, respectively) and non-menstrual pelvic pain in women with endometriosis (58.5% vs. 39.6% and 66.0% vs. 42.7% for SPIRIT 1 and 2, respectively) compared with placebo ( $p < 0.0001$  for both co-primary endpoints in both studies). Dysmenorrhea rapidly decreased from severe at baseline to mild by Week 8 which was sustained through Week 24. Non-menstrual pelvic pain decreased from moderate at baseline to mild over 24 weeks. Both studies also met several key secondary endpoints including reduction in dyspareunia (painful intercourse) and the EHP-30 pain domain. Changes in bone mineral density over 24 weeks were minimal in the relugolix combination therapy group.

### Details of the presentations from studies of women with uterine fibroids are as follows:

The Phase 3 LIBERTY program evaluated the efficacy and safety of once-daily relugolix combination therapy in premenopausal women with heavy menstrual bleeding associated with uterine fibroids in two replicate studies, LIBERTY 1 and 2. The primary endpoint of both studies was met with a significant proportion of women treated with relugolix combination therapy achieving the responder criteria for reduction in menstrual blood loss compared with placebo after 24 weeks of treatment ( $p < 0.0001$  in both studies). Eligible women who completed the studies were offered the opportunity to enroll in an active treatment extension study in which all women received relugolix combination therapy for an additional 28-week period, for a total treatment period of 52 weeks.

- **LIBERTY: Long-Term Extension Study Demonstrating One-Year Efficacy and Safety of Relugolix Combination Therapy in Women with Symptomatic Uterine Fibroids** (oral presentation, O-1, Scientific Congress Prize Paper Session 1)

In this first presentation of detailed data from the LIBERTY long-term extension study, 87.7% of women achieved the responder criteria for reduction in menstrual blood loss at one year. Women experienced, on average, a 90% reduction in menstrual blood loss from baseline at one year, with most women (70.6%) achieving amenorrhea. In addition, 59% of women with anemia at baseline experienced anemia improvement at one year. Lumbar spine and total hip bone mineral density were maintained over one year. The adverse event profile with relugolix combination therapy over one year was consistent with that observed in LIBERTY 1 and 2.

- **Quality-of-Life Improvement with Relugolix Combination Therapy in Patients with Heavy Menstrual Bleeding Associated with Uterine Fibroids: Results from the LIBERTY Phase 3 Program** (oral presentation, O-205)

In this pooled analysis of data from the LIBERTY 1 and 2 studies, women who received relugolix combination therapy experienced a significantly greater reduction in symptom severity (scale from 0 to 100 with higher scores indicating worse outcomes) from baseline to Week 24 than women receiving placebo (33.5 vs. 12.1, nominal  $p < 0.0001$ ). Women who received relugolix combination therapy also experienced a significantly greater improvement in total quality of life scores (scale from 0 to 100 with higher scores indicating better outcomes) from baseline to Week 24 compared to women receiving placebo (37.6 vs. 13.1, nominal  $p < 0.0001$ ), which included assessment of daily activities, emotional wellbeing, and sexual function.

- **Relugolix Combination Therapy Significantly Reduced Menstrual Blood Loss with First Treatment Cycle in Women with Heavy Menstrual Bleeding Associated with Uterine Fibroids: Results from the LIBERTY Phase 3 Program** (oral presentation, O-206)

In this pooled analysis of data from the LIBERTY 1 and 2 studies, women who received relugolix combination therapy experienced a significantly greater reduction in menstrual blood volume in their first cycle compared to women who received placebo (52.4% vs. 14.7%, nominal  $p < 0.0001$ ). At Week 24, the reduction for women in the relugolix combination therapy group was 84.7% compared with 19.5% in the placebo group (nominal  $p < 0.0001$ ).

- **Relugolix Combination Therapy Improves Uterine Fibroid-Associated Pain During Menstrual and Non-Menstrual Days: Results from the LIBERTY Phase 3 Program** (poster presentation, P-308, 1<sup>st</sup> Place in Poster Competition)

In this pooled analysis of data from the LIBERTY 1 and 2 studies, after 24 weeks of treatment, the proportion of women reporting minimal-to-no uterine fibroid-associated pain (maximum score of 1 on a 0 to 10 Numerical Rating Scale) during the last 35 days of treatment was significantly greater for women who received relugolix combination therapy versus placebo (45.2% vs. 13.9%, nominal  $p < 0.0001$ ). The reduction of uterine fibroid-associated pain with relugolix combination therapy was rapid and sustained over time. Improvement of pain associated with uterine fibroids was demonstrated both during menstrual and non-menstrual days.

Details of presentations from additional studies are as follows:

- **Characterization of Pituitary and Ovarian Hormone Concentrations During Treatment with Relugolix Combination Therapy** (oral presentation, O-196)

In a Phase 1 open-label, single-arm ovulation inhibition study, 67 healthy premenopausal women were evaluated over an 84-day treatment period (three cycles) to assess the effects of relugolix combination therapy on ovulation inhibition. During the study, relugolix combination therapy consistently suppressed pituitary and ovarian hormone concentrations, follicular growth, and endometrial proliferation, and resulted in 100% ovulation inhibition, with 100% return to ovulation or menses after discontinuation of treatment.

- **Simulated Long-Term Effects of Relugolix Combination Therapy on Bone Mineral Density at the Lumbar Spine as Projected by a Validated Semi-Mechanistic Exposure-Response Model** (poster presentation, P-598)

To evaluate bone mineral density change associated with estradiol (E2) concentrations, a semi-mechanistic, exposure-response model was developed to describe bone mineral density change in the lumbar spine over time as a function of E2 concentrations in women with uterine fibroids or endometriosis. Simulations from this model were well correlated with the effect of relugolix combination therapy observed in the Phase 3 LIBERTY program and projected maintenance of bone mineral density with relugolix combination therapy in women with uterine fibroids for at least three years.

Relugolix combination tablet is under review by the U.S. Food and Drug Administration (FDA) for the treatment of women with uterine fibroids, with a target action date of June 1, 2021. Myovant submitted a Marketing Authorization Application to the European Medicines Agency in March 2020 for relugolix combination tablet in uterine fibroids. Additionally, relugolix (120 mg) is under Priority Review by the FDA for the treatment of men with advanced prostate cancer, with a target action date of December 20, 2020.

#### About Relugolix

Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces ovarian estradiol, a hormone known to stimulate the growth of uterine fibroids and endometriosis, and testicular testosterone, a hormone known to stimulate the growth of prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review in Europe and the U.S. for women with uterine fibroids and is under development for women with endometriosis. Relugolix monotherapy tablet (120 mg) is under regulatory review in the U.S. for men with advanced prostate cancer.

#### About Myovant Sciences

Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Our lead product candidate, relugolix, is a once-daily, oral GnRH receptor antagonist. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review in Europe and the U.S. for women with uterine fibroids and is under development for women with endometriosis. Relugolix monotherapy tablet (120 mg) is under regulatory review in the U.S. for men with advanced prostate cancer. We are also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for female infertility as part of assisted reproduction. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is our majority shareholder. For more information, please visit our website at [www.myovant.com](http://www.myovant.com). Follow [@Myovant](https://twitter.com/Myovant) on Twitter and [LinkedIn](https://www.linkedin.com/company/myovant).

#### Forward-Looking Statements

This press-release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking

statements include all statements regarding Myovant Sciences' intent, belief, or expectations regarding future events or results and can be identified by words such as "anticipate," "aspire," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words or other similar expressions or variations, although not all forward-looking statements contain these identifying words. In this press release, forward-looking statements include, but are not limited to, statements and quotes regarding Myovant Sciences' aspirations to redefine care for women and for men; Myovant's vision for a one pill, once-a-day treatment that provides symptom relief with minimal side effects, potentially allowing for long-term treatment of women suffering from these common and chronic conditions; the characterizations of the data presented at the American Society for Reproductive Medicine (ASRM) 2020 Virtual Congress; the FDA target action date of December 20, 2020 under the Prescription Drug User Fee Act (PDUFA) for Myovant's NDA for the treatment of men with advanced prostate cancer and the target action date of June 1 for Myovant's NDA for the treatment of women with uterine fibroids. Myovant Sciences' forward-looking statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could materially affect Myovant Sciences' operations and future prospects or which could cause actual results to differ materially from expectations include, but are not limited to the risks and uncertainties listed in Myovant Sciences' filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Myovant Sciences' Quarterly Report on Form 10-Q filed on August 11, 2020, as such risk factors may be amended, supplemented or superseded from time to time. These risks are not exhaustive. New risk factors emerge from time to time. You should not place undue reliance on the forward-looking statements in this press release, which speak only as of the date hereof, and, except as required by law, Myovant Sciences undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

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