



Myovant Sciences Announces Positive Results from Phase 3 SPIRIT 2 Study Evaluating Once-Daily Relugolix Combination Therapy in Women with Endometriosis and from Ovulation Inhibition Study

April 22, 2020

- *Co-primary endpoints met with 75.2% response rate for dysmenorrhea (menstrual pain) ($p < 0.0001$) and 66.0% response rate for non-menstrual pelvic pain ($p < 0.0001$)*
- *Women receiving relugolix combination therapy, on average, had a 75.1% reduction on the Numerical Rating Scale for dysmenorrhea from 7.2 (severe pain) to 1.7 (mild pain)*
- *Achieved six key secondary endpoints, including improvement in impact of pain on daily activities and a greater proportion of women not using opioids, with a generally well-tolerated safety profile including minimal bone mineral density loss*
- *Demonstrated 100% ovulation inhibition and 100% return of ovulation or menses upon discontinuation of treatment in a separate study*
- *Conference call and webcast to be held today at 8:30 a.m. EDT / 5:30 a.m. PDT*

BASEL, Switzerland, April 22, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women's health and prostate cancer, today announced that SPIRIT 2, the first of two Phase 3 studies of once-daily relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg, and norethindrone acetate 0.5 mg) in women with pain associated with endometriosis, met its co-primary efficacy endpoints and six key secondary endpoints. In addition, relugolix combination therapy was generally well-tolerated including minimal bone mineral density loss over 24 weeks.

Myovant also announced that, in a separate clinical study, relugolix combination therapy achieved 100% ovulation inhibition in 67 healthy women with no women ovulating during the 84-day treatment period, as evaluated by the Hoogland-Skouby assessment scale (score < 5). Furthermore, 100% of women resumed ovulation or menses upon discontinuation of treatment with an average time to ovulation of 23.5 days.

"Endometriosis causes severe physical pain and emotional distress for many women who are in need of new non-invasive treatment options suitable for long-term use," said Linda Giudice, M.D., Ph.D., distinguished professor in reproductive sciences at the University of California, San Francisco (UCSF). "The clinically-meaningful results announced today are highly encouraging, especially since the same dose that achieved significant improvement in pain also demonstrated a well-tolerated safety profile including minimal bone mineral density loss."

In the co-primary endpoint analysis of SPIRIT 2, 75.2% of women receiving once-daily relugolix combination therapy achieved a clinically-meaningful reduction in dysmenorrhea versus 30.4% of women in the placebo group ($p < 0.0001$). For non-menstrual pelvic pain, relugolix combination therapy achieved a clinically-meaningful reduction in 66.0% of women versus 42.6% women in the placebo group ($p < 0.0001$). On average, women receiving relugolix combination therapy had a 75.1% reduction on the 11-point (0 to 10) Numerical Rating Scale for dysmenorrhea from 7.2 (severe pain) to 1.7 (mild pain).

"Building on our successful Phase 3 studies in uterine fibroids, we are very pleased with the positive results from our first Phase 3 study in endometriosis which brings us closer to realizing our vision of a one dose, one pill, once a day potential treatment that balances clinically-meaningful symptom relief with a well-tolerated safety profile for women suffering from these diseases," said Lynn Seely, M.D., chief executive officer of Myovant Sciences. "We look forward to sharing the results from our replicate Phase 3 study in endometriosis later this quarter."

Six key secondary endpoints measured at Week 24 and compared to placebo achieved statistical significance, including changes in mean dysmenorrhea and overall pelvic pain, impact of pain on daily activities as measured by the Endometriosis Health Profile-30 (EHP-30) pain domain, a greater proportion of women not using opioids (all p -values < 0.0001), changes in non-menstrual pelvic pain ($p = 0.0012$), and dyspareunia (painful intercourse) ($p = 0.0489$).

Relugolix combination therapy was generally well-tolerated with minimal bone mineral density loss over 24 weeks. The overall incidence of adverse events in the relugolix combination and placebo groups was similar (80.6% vs. 75.0%). In the relugolix combination therapy group, 5.3% of women discontinued treatment early due to adverse events versus 3.9% in the placebo group. The most frequently reported adverse events, reported in at least 10% of women in the relugolix combination group, were headache, nasopharyngitis, and hot flashes. There were three pregnancies in the relugolix combination group and five in the placebo group.

Conference Call

Myovant will hold a conference call today, Wednesday, April 22, 2020 beginning at 8:30 a.m. EDT / 5:30 a.m. PDT to discuss results of the clinical studies. The dial in numbers are 1-800-532-3746 for domestic callers and +1-470-495-9166 for international callers. A live webcast of the conference call will also be available on the investor relations page of Myovant's website at investors.myovant.com. After the live webcast, the event will remain archived on Myovant's website for at least 30 days.

About the Phase 3 SPIRIT Program in Endometriosis

Myovant's Phase 3 clinical program for endometriosis consists of two multinational, replicate pivotal clinical studies (SPIRIT 1 and SPIRIT 2) of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with pain associated with endometriosis. Women received treatment either with relugolix combination therapy for 24 weeks, relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix combination therapy once daily for an additional 12 weeks, or placebo once daily for 24 weeks. Eligible women who completed the SPIRIT 1 or SPIRIT 2 studies were offered the opportunity to enroll in an active treatment extension study in which all women receive relugolix combination therapy for an additional 80-week period, resulting in a total treatment period of up to 104 weeks, designed to evaluate the safety

and sustained efficacy of longer-term treatment.

About the Ovulation Inhibition Study

The ovulation inhibition study was a Phase 1 open-label, single-arm study consisting of a pre-treatment period to confirm ovulatory status, an 84-day treatment period (three cycles) to assess the effects of relugolix combination therapy on ovulation inhibition, and a post-treatment follow-up period to determine the time to the return of ovulation. Ovulation inhibition was based on the Hoogland-Skouby scale.

About Endometriosis

Endometriosis is an estrogen-dependent, inflammatory disease in which tissue similar to the uterine lining is found outside the uterine cavity, commonly in the lower abdomen or pelvis, on ovaries, the bladder, and the colon. This endometrial-like 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 hormonal contraceptives and over-the-counter pain medications. In more severe cases, GnRH agonists such as leuprolide acetate are used for short-term treatment. An estimated six million women in the U.S. suffer from symptoms of endometriosis, and an estimated one million women are inadequately treated by current medical therapy and require further treatment. Almost 200 million women are affected globally.

About Relugolix

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

About Myovant Sciences

Myovant Sciences aspires to be the leading healthcare company focused on redefining care for women's health and prostate cancer. The company's lead product candidate is relugolix, a once-daily, oral GnRH receptor antagonist. The company has three late-stage clinical programs for relugolix in uterine fibroids, endometriosis, and prostate cancer. The company is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, that has completed a Phase 2a study for the treatment of female infertility as part of assisted reproduction. Takeda Pharmaceuticals International AG, a subsidiary of Takeda Pharmaceutical Company Limited, the originator of relugolix, previously granted the company a worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive license to develop and commercialize MVT-602 in all countries worldwide. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is the majority shareholder of Myovant. For more information, please visit the company's website at www.myovant.com. Follow [@Myovant](https://twitter.com/Myovant) on Twitter and [Linkedln](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 become the leading healthcare company focused on redefining care for women's health and prostate cancer; statements summarizing and characterizing data from the SPIRIT 2 and ovulation inhibition studies; the expected timing of results from the second Phase 3 study in endometriosis (SPIRIT 1); Myovant's vision of a one dose, one pill, once a day treatment that balances clinically meaningful symptom relief with a well-tolerated safety profile for women suffering from endometriosis and uterine fibroids; and the estimated market size for endometriosis and commercial potential for relugolix combination tablet for the treatment of women with endometriosis. 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. Myovant Sciences cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these 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 February 10, 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 and it is not possible for Myovant Sciences' management to predict all risk factors, nor can Myovant Sciences assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. 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.

Investor Contact:

Frank Karbe
President, Chief Financial Officer
Myovant Sciences, Inc.
investors@myovant.com

Media Contact:

Albert Liao
Director, Corporate Communications
Myovant Sciences, Inc.
media@myovant.com



Source: Myovant Sciences, Inc.