Myovant Sciences Announces Publication of Abstracts Detailing Additional Efficacy and Safety Findings from Phase 3 LIBERTY Studies in Uterine Fibroids in Obstetrics & Gynecology

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- *Abstracts accepted for presentation in oral and poster sessions at the 2020 American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting*
- *Treatment with relugolix combination therapy resulted in significant improvements in pain and quality of life in women with heavy menstrual bleeding associated with uterine fibroids*
- *Relugolix combination therapy preserved bone mineral density over 24 weeks compared with relugolix monotherapy*

BASEL, Switzerland, April 27, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women's health and prostate cancer, today announced that the journal *Obstetrics & Gynecology* has published three abstracts detailing additional efficacy and safety findings from the Phase 3 LIBERTY 1 and 2 studies of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with heavy menstrual bleeding associated with uterine fibroids. The abstracts were originally accepted for presentation in oral and poster sessions at the American College of Obstetricians and Gynecologists (ACOG) 2020 Annual Clinical and Scientific Meeting, which was cancelled due to the COVID-19 pandemic.

"These additional findings reinforce the positive impact on pain and quality of life achieved by relugolix combination therapy in the LIBERTY studies in women suffering from uterine fibroids," said Juan Camilo Arjona Ferreira, M.D., chief medical officer of Myovant Sciences. "Relugolix combination therapy also preserved bone mineral density over 24 weeks of treatment, again demonstrating the potential for a new treatment option that may provide clinically-meaningful symptom relief and maintain bone health."

Abstracts are available in *Obstetrics & Gynecology*. Details of the abstracts are as follows.

Relugolix Combination Therapy Reduced Uterine Fibroid-Associated Pain in Two Phase 3 LIBERTY Studies (Abstract #32B)

The pain-evaluable population included 127 and 150 women from LIBERTY 1 and 2 studies, respectively, who experienced moderate to severe pain before randomization and completed the 24-week study. In an analysis of pooled data:

- 65% of women treated with relugolix combination therapy reported no or minimal pain during menstrual days (maximum score of 1 on a 0 to 10 Numerical Rating Scale) compared to 19.3% for women in the placebo group.
- 44.6% of women treated with relugolix combination therapy reported no or minimum pain during non-menstrual days, compared to 21.6% of women in the placebo group.

Relugolix Combination Improves Quality of Life in Phase 3 Studies of Symptomatic Uterine Fibroids (Abstract #OP04-4D)

Women in both LIBERTY 1 and LIBERTY 2 studies completed the validated Uterine Fibroid Symptom (UFS)-Quality of Life (QoL) questionnaire:

- Women treated with relugolix combination therapy experienced significant improvement in symptom severity (scale from 0 to 100 with higher scores indicating worse outcomes) from baseline to Week 24 (both studies $p < 0.0001$) from 55.1 to 23.4 compared with 60.3 to 49.2 for women in the placebo group in LIBERTY 1, and from 59.1 to 21.7 compared with 59.2 to 45.1 for women in the placebo group in LIBERTY 2.
- Health-related QoL (scale from 0 to 100 with higher scores indicating better outcomes) also improved significantly for women treated with relugolix combination therapy from baseline to Week 24 (both studies $p < 0.0001$) from 37.2 to 74.0 compared with 33.5 to 44.9 for women in the placebo group in LIBERTY 1, and from 38.9 to 78.7 compared with 37.3 to 51.0 for women in the placebo group in LIBERTY 2.

Bone Mineral Density Assessment with Relugolix Combination Therapy: Results from the Phase 3 LIBERTY Program (Abstract #OP04-2D)

Results demonstrated that relugolix combination therapy preserved bone mineral density over 24 weeks in the LIBERTY program. In contrast, relugolix monotherapy for 12 weeks was associated with bone mineral density loss, which stabilized upon transition to relugolix combination therapy for 12 weeks. These data suggest that initiating treatment for uterine fibroids with relugolix combination therapy represents a potential treatment option for preserving bone mineral density while providing long-term therapeutic benefit.

- In LIBERTY 1, treatment with relugolix combination therapy resulted in a -0.36% mean change from baseline at Week 24 in lumbar spine bone mineral density, compared to a -1.82% mean change for women who started on relugolix monotherapy, and 0.05% change for women in the placebo group.
- In LIBERTY 2, treatment with relugolix combination therapy resulted in a -0.13% mean change from baseline at Week 24 in lumbar spine bone mineral density, compared to a -2.12% mean change for women who started on relugolix monotherapy, and -0.32% change for women in the placebo group.

About the Phase 3 LIBERTY Program in Uterine Fibroids
Myovant's Phase 3 clinical program for uterine fibroids consisted of two multinational, replicate pivotal clinical studies (LIBERTY 1 and LIBERTY 2) of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with heavy menstrual bleeding associated with uterine fibroids. 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 LIBERTY 1 or LIBERTY 2 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, designed to evaluate the safety and sustained efficacy of longer-term treatment. Upon completion of this 52-week total treatment period, eligible women could elect to participate in a second 52-week randomized withdrawal study designed to provide two-year safety and efficacy data on relugolix combination therapy and to evaluate the need for maintenance therapy.

About Uterine Fibroids
Affecting over 25% of women of reproductive age, uterine fibroids are noncancerous tumors that develop in or on the muscular walls of the uterus and are among the most common reproductive tract tumors in women. In addition to an individual's genetic predisposition, estrogens are well known to play an important role in the regulation of fibroid growth.

Although uterine fibroids are benign tumors, they can cause debilitating symptoms such as heavy menstrual bleeding (frequently resulting in anemia and fatigue), pain (including painful periods, abdominal pain, painful intercourse, backache), increased abdominal girth and bloating, urinary frequency or retention, constipation, pregnancy loss, and, in some cases, infertility. These symptoms can also lead to loss of productivity at work, limitations in normal activities of daily living, and social embarrassment.

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 on Twitter and LinkedIn.

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 be the leading healthcare company focused on redefining care for women's health and prostate cancer ; characterizations and quotes regarding the LIBERTY studies, including the positive impact on pain and quality of life achieved by relugolix combination therapy in the LIBERTY studies and the preservation of bone mineral density over 24 weeks of treatment; and the potential for a new treatment option that may provide clinically-meaningful symptom relief and maintain bone health. 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.

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