# Myovant Sciences Announces Late-Breaking Oral Presentation of Phase 3 LIBERTY 1 & 2 Study Results at 2019 American Society for Reproductive Medicine Scientific Congress

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BRISBANE, Calif., and BASEL, Switzerland, Oct. 10, 2019 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on developing innovative treatments for women's health and prostate cancer, today announced that results from its Phase 3 LIBERTY 1 & 2 studies of relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids will be presented in the late-breaking oral session at the 2019 American Society for Reproductive Medicine (ASRM) Scientific Congress, which is being held October 12-16 in Philadelphia, Pennsylvania.

Both Phase 3 studies met their primary efficacy endpoint with relugolix combination therapy demonstrating significant reduction in heavy menstrual bleeding ($p < 0.0001$) in women with uterine fibroids. Key secondary endpoints including a reduction in mean menstrual blood loss volume, achievement of amenorrhea (defined as no or negligible menstrual bleeding), reduction in pain associated with uterine fibroids, improvement in anemia, reduction in distress from bleeding and pelvic discomfort, and reduction in uterine volume were also met in both studies with statistical significance. The safety profile of relugolix combination therapy in both studies was generally well-tolerated with bone health maintained and vasomotor symptoms comparable to those in the placebo group.

In addition, Myovant Sciences will present a poster on the development and validation of the bleeding and pelvic discomfort scale, a patient-reported outcome for women with heavy menstrual bleeding associated with uterine fibroids.

Presentation details are as follows:

**Oral Presentation**

Session: OR03-15 - Late-Breaking 1
Title: Treatment of Symptoms of Uterine Fibroids with Relugolix Combination Therapy: Efficacy and Safety Results from the Phase 3 LIBERTY 1 Clinical Trial
Abstract #: O-265
Presenter: Ayman Al-Hendy, MD, PhD, University of Illinois College of Medicine
Session Date & Time: Wednesday, October 16, 12:00 p.m. EDT
Location: Pennsylvania Convention Center – Exhibit Hall C

**Poster Presentation**

Session: Poster Session 2; P02-16 - Fibroids
Title: Measuring Patient-Reported Outcomes in Women with Heavy Menstrual Bleeding Associated with Uterine Fibroids: The Bleeding and Pelvic Discomfort Scale
Abstract #: P-595
Presenter: Juliet Li, PhD, Myovant Sciences
Session Date & Time: Wednesday, October 16, 6:30–7:45 a.m. EDT
Location: Pennsylvania Convention Center – Expo Hall

**Phase 3 LIBERTY Program**

Myovant Sciences' 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 uterine fibroids and heavy menstrual bleeding. Women in the LIBERTY 1 and LIBERTY 2 studies underwent a screening period requiring up to two menstrual cycles to document heavy menstrual bleeding and were randomized in a 1:1:1 ratio to one of three groups. 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.

Myovant Sciences enrolled 388 women in LIBERTY 1 and 382 women in LIBERTY 2. To be enrolled, women must have had a monthly menstrual blood loss volume of at least 80 mL in two consecutive cycles or 160 mL in one cycle, measured by the alkaline hematin method, a quantitative measure of menstrual blood loss from an assessment of collected menstrual products.

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 receive 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 can 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**

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, estrogen and progesterone 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 abnormal uterine bleeding, heavy or painful periods, anemia, abdominal pain, backache, increased abdominal girth and bloating, urinary frequency or retention, constipation or painful defecation,

pregnancy loss, painful intercourse 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.

An estimated 5 million women in the U.S. suffer from symptoms of uterine fibroids, and an estimated 3 million women are inadequately treated by current medical therapy and require further treatment.

**About Relugolix**
Relugolix is a once daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces ovarian estradiol and progesterone production, hormones known to stimulate the growth of uterine fibroids.

Myovant Sciences is also studying relugolix combination therapy in two Phase 3 clinical studies (SPIRIT 1 and SPIRIT 2) evaluating endometriosis-associated pain. Relugolix monotherapy, 120 mg once daily, is also being evaluated in the Phase 3 HERO study in men with advanced prostate cancer.

**About Myovant Sciences**
Myovant Sciences aspires to be the leading healthcare company focused on innovative treatments for women's health and prostate cancer. Myovant Sciences' lead product candidate is relugolix, an oral, once-a-day small molecule that acts as a GnRH receptor antagonist. Myovant Sciences has three late-stage clinical programs for relugolix ongoing in uterine fibroids, endometriosis, and prostate cancer. Myovant Sciences 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 granted Myovant Sciences an exclusive, 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. For more information, please visit Myovant Sciences' website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn.

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