Myovant Sciences Initiates Phase 3 Clinical Program of Relugolix in Women With Heavy Menstrual Bleeding Associated With Uterine Fibroids

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BASEL, Switzerland, Jan. 25, 2017 /PRNewswire/ -- Myovant Sciences (NYSE: **MYOV**) today announced it has initiated a Phase 3 clinical program consisting of two international clinical trials, LIBERTY 1 and LIBERTY 2, to evaluate the safety and efficacy of relugolix in women with heavy menstrual bleeding associated with uterine fibroids. Relugolix is an oral, once-daily, small molecule gonadotropin-releasing hormone (GnRH) receptor antagonist that decreases estrogen and progesterone. It will be evaluated with and without low-dose hormonal add-back therapy.

"Millions of women worldwide suffer from heavy menstrual bleeding associated with uterine fibroids that can result in anemia and fatigue, limitation of daily activities, and social embarrassment," said Ayman Al-Hendy, MD, Professor of Obstetrics & Gynecology, Medical College of Georgia at Augusta University. "There is a great need for new medicines to treat this benign condition so women have alternatives to hysterectomy and other invasive procedures."

About the Phase 3 Studies
LIBERTY 1 and LIBERTY 2 are double-blind, placebo-controlled Phase 3 international clinical trials in women with heavy menstrual bleeding associated with uterine fibroids that will be conducted at up to 200 sites. Each of the two clinical trials is expected to enroll approximately 390 women aged 18 to 50 years with a diagnosis of uterine fibroids confirmed by ultrasound and heavy menstrual bleeding attributed to uterine fibroids. Eligible women will be randomized to one of three groups: relugolix 40 mg orally once daily co-administered with low-dose hormonal add-back therapy (1 mg estradiol/0.5 mg norethindrone acetate) for 24 weeks, relugolix 40 mg orally once daily monotherapy for 12 weeks followed by relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 12 weeks, or placebo once daily for a period of 24 weeks. Patients completing the initial 24-week blinded assessment will be offered an active treatment extension with relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 24-week period, or a total treatment period of up to 48 weeks, to evaluate the safety of longer-term treatment.

The primary efficacy outcome of the study is a clinically-meaningful reduction in menstrual blood loss based upon the alkaline hematin method, a standardized centrally-assessed quantitative measurement of menstrual blood loss. Safety outcomes, including bone mineral density changes as measured by dual-energy x-ray absorptiometry, will also be assessed.

"The initiation of our relugolix Phase 3 clinical program in women with uterine fibroids is an important milestone for Myovant as we work towards our mission of becoming a global leader in women's health and endocrinology," said Lynn Seely, MD, President & Chief Executive Officer of Myovant Sciences, Inc. "The initiation of this trial ahead of schedule demonstrates our commitment to bring new treatments to women suffering from uterine fibroids and endometriosis as efficiently and rapidly as possible."

Myovant intends to initiate five Phase 3 clinical trials for relugolix in 2017. In the first half of the year, the company plans to initiate two international Phase 3 trials for relugolix co-administered with and without low-dose hormonal add-back therapy in women with endometriosis-associated pain. In addition, Myovant anticipates launching an international Phase 3 clinical trial for relugolix in men with advanced prostate cancer during the first quarter of 2017.

About Uterine Fibroids
Uterine fibroids are non-cancerous tumors composed of smooth muscle and fibrous connective tissue that develop in or on the walls of the uterus. In addition to an individual's genetic predisposition, estrogens and progesterone play important roles in the regulation of fibroid growth. Although uterine fibroids are benign tumors that are often asymptomatic, they can cause debilitating symptoms such as abnormal uterine bleeding, heavy or painful menstrual 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. Uterine fibroids are among the most common benign reproductive tract tumors in women. It is estimated that approximately 5 million women in the United States alone suffer from symptomatic uterine fibroids.

About Relugolix
Relugolix is an oral, once-daily, small molecule that acts as a 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 has been shown to be generally well tolerated and to suppress estrogen and progesterone levels in women and testosterone levels in men. Common side effects are consistent with the lowering of estrogen and progesterone in women and testosterone in men. In the Phase 3 LIBERTY clinical trials in women with uterine fibroids, relugolix will be evaluated with and without low-dose hormonal add-back therapy, which is expected to decrease potential side effects such as bone mineral density loss and hot flashes.

About Myovant Sciences
Myovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health diseases and other endocrine-related disorders. Myovant's lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a GnRH

receptor antagonist. Myovant is in the process of initiating five international Phase 3 clinical trials for relugolix, two in women with heavy menstrual bleeding associated with uterine fibroids, two in women with endometriosis-associated pain, and one in men with advanced prostate cancer. 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-related disorders. 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 ability to advance the clinical development of its lead product candidate, relugolix, into Phase 3 clinical development in multiple indications and expand its development pipeline. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. 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 affecting Myovant, see Myovant's publicly available filings with the U.S. Securities and Exchange Commission, including its Quarterly Report on Form 10-Q filed on December 9, 2016. 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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