Myovant Sciences Initiates Phase 3 Clinical Program of Relugolix in Women with Endometriosis-Associated Pain

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BASEL, Switzerland, June 29, 2017 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV) today announced it has initiated a Phase 3 clinical program consisting of two international clinical trials, SPIRIT 1 and SPIRIT 2, to evaluate the efficacy and safety of relugolix in women with endometriosis-associated pain. Relugolix is an oral, once-daily, small molecule gonadotropin-releasing hormone (GnRH) receptor antagonist that decreases estrogen and progesterone. Relugolix will be evaluated with and without low-dose hormonal add-back therapy.

"Endometriosis is a very common and debilitating estrogen-driven disease that occurs in around ten percent of pre-menopausal women," said Linda C. Giudice, MD, PhD, a reproductive endocrinologist and Distinguished Professor at the University of California, San Francisco School of Medicine. "Women with moderate to severe endometriosis-associated pain are in great need of well-tolerated medicines to help ease their pain and provide a treatment alternative to invasive procedures such as laparoscopy and hysterectomy."

About the Phase 3 Studies

SPIRIT 1 and SPIRIT 2 are randomized, double-blind, placebo-controlled, international Phase 3 clinical trials in women with endometriosis-associated pain. Each of the two clinical trials is expected to enroll approximately 600 women aged 18 to 50 years with a diagnosis of endometriosis confirmed by laparoscopy or laparotomy. 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. Eligible 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 28-week period, resulting in a total treatment period of up to 52 weeks, to evaluate the safety of longer-term treatment.

The co-primary efficacy endpoints of the SPIRIT 1 and SPIRIT 2 trials are:

- the proportion of women with reduction in dysmenorrhea (menstrual pelvic pain), as assessed by a daily endometriosis-specific patient questionnaire, without an increase in background pain medication; and
- the proportion of women with reduction in non-menstrual pelvic pain, as assessed by a daily endometriosis-specific patient questionnaire, without an increase in background pain medication

Safety outcomes, including bone mineral density changes as measured by dual-energy x-ray absorptiometry, will also be assessed.

"With the initiation of the SPIRIT program, Myovant will be running five ongoing Phase 3 trials for relugolix in three critical areas of unmet medical need," said Lynn Seely, MD, President & Chief Executive Officer of Myovant Sciences, Inc. "I could not be prouder of the dedication and resourcefulness shown by our entire team in achieving our ambitious development timelines."

Myovant announced the initiation of a program evaluating relugolix with and without low-dose hormonal add-back therapy in women with uterine fibroids in January 2017. That program consists of two international Phase 3 trials, LIBERTY 1 and LIBERTY 2, which will enroll approximately 390 patients each. In addition, Myovant announced the launch of an international Phase 3 clinical trial for relugolix in men with advanced prostate cancer in March 2017. That trial, HERO, will enroll approximately 1,125 patients.

About Endometriosis

Endometriosis is a 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 oral contraceptives and over-the-counter pain medications. In more severe cases, GnRH agonists such as leuprolide acetate are used for short-term treatment. It is estimated that one in ten women between the ages of 15 and 49 have endometriosis, including approximately 6 million women in the United States suffering from symptomatic endometriosis, approximately 1.2 million of whom are inadequately treated by oral contraceptives and require additional treatment.

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, and common side effects are consistent with suppression of these hormones. In the Phase 3 SPIRIT clinical trials in women with endometriosis-associated pain, 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 and other endocrine diseases. Myovant's lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a GnRH receptor antagonist. Myovant has now initiated three clinical programs for relugolix consisting of five international Phase 3 clinical trials, 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, a kisspeptin agonist, 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 diseases. 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 Annual Report on Form 10-K filed on June 14, 2017. 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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