Myovant Sciences Announces Completion of Screening for Phase 3 LIBERTY 1 Study Evaluating Relugolix in Women with Uterine Fibroids

July 10, 2018

- Top-line data for LIBERTY 1 expected in second quarter of 2019- Myovant on track to announce top-line results from all relugolix Phase 3 clinical studies in uterine fibroids, endometriosis and prostate cancer during 2019- Company to present at first annual Roivant Pipeline Day today, Tuesday, July 10, 2018, at 2:30 p.m. ET.

BASEL, Switzerland, July 10, 2018 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV), a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health and endocrine diseases, today announced that it has completed screening patients for its LIBERTY 1 study, the first of two Phase 3 replicate studies evaluating relugolix in women with heavy menstrual bleeding associated with uterine fibroids.

Uterine fibroids are debilitating and result in heavy menstrual bleeding in millions of women throughout the world, often requiring a hysterectomy. Myovant is working to develop relugolix, an oral, once-daily medication, to potentially provide women with an alternative to invasive procedures and major surgery for the treatment of uterine fibroids.

"Completion of screening for LIBERTY 1 is a critical milestone for our uterine fibroids program," said Lynn Seely, M.D., President and CEO of Myovant. "We look forward to completing screening for LIBERTY 2 this quarter and reporting top-line efficacy and safety data for LIBERTY 1 in the second quarter of 2019. Today's announcement is the first of several milestones we expect to report as we continue to diligently work toward top-line results on all of our ongoing Phase 3 clinical studies during 2019."

In addition, Dr. Seely will present on behalf of Myovant at the first annual Roivant Pipeline Day today, Tuesday, July 10, 2018, at 2:30 p.m. ET. A live webcast will be available via the Events page under the Investors and Media section of Myovant's website at www.myovant.com. Please connect to the company's website at least 15 minutes prior to the presentation to ensure adequate time for any software download that may be required to listen to the webcast. A replay as well as the slide presentation will be available at the same location for 30 days following the conference.

About Myovant's Phase 3 Program for Uterine Fibroids
Myovant is currently conducting a Phase 3 clinical program consisting of two international, replicate pivotal clinical trials (LIBERTY 1 and LIBERTY 2), initiated in January 2017, of relugolix in women with heavy menstrual bleeding associated with uterine fibroids. Women with heavy menstrual bleeding associated with uterine fibroids in the LIBERTY 1 and LIBERTY 2 trials undergo a screening period requiring up to two menstrual cycles to document heavy menstrual bleeding and are then randomized in a 1:1:1 ratio to one of three arms. Women receive treatment with relugolix 40 mg once daily co-administered with commercially available hormonal add-back therapy for 24 weeks, relugolix 40 mg 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. Myovant expects to enroll approximately 390 women in each of the two replicate LIBERTY 1 and LIBERTY 2 trials, with 130 women in each of the two active treatment arms and 130 women in the placebo arm. To be enrolled, women must have a monthly menstrual blood loss of at least 80 mL, measured by the alkaline hematin method, a quantitative measure of menstrual blood loss.

The primary efficacy endpoint for LIBERTY 1 and LIBERTY 2 is the proportion of all women enrolled who achieve a menstrual blood loss volume of less than 80 mL and at least a 50 percent reduction in menstrual blood loss volume from baseline over the last month of treatment as measured by the alkaline hematin method. Secondary efficacy endpoints include measures of change from baseline in hemoglobin, assessment of the impact of therapy on quality-of-life measures, reduction in uterine and fibroid volume, and pain reduction. Safety, including bone mineral density changes as measured by dual-energy x-ray absorptiometry, is also being assessed.

Eligible women completing the LIBERTY 1 or LIBERTY 2 trial will be offered the opportunity to enroll in an active treatment extension study in which all patients will receive relugolix 40 mg once daily co-administered with hormonal add-back therapy for an additional 28-week period, for a total treatment period of 52 weeks, to evaluate the safety and sustained efficacy of longer-term treatment.

If the results of LIBERTY 1 and LIBERTY 2 are favorable, Myovant intends to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in 2019.

About Roivant Pipeline Day
Roivant Pipeline Day will be held today, Tuesday, July 10, 2018, in New York City. The event will feature presentations, fireside chats, and Q&A sessions from executives across the Roivant family of companies. The event is scheduled to begin at 2:00 p.m. ET and will continue until approximately 5:30 p.m. ET. Due to limited capacity, attendance is by invitation only but a live webcast will be available to interested parties. To request access to the webcast or to learn more about the event, please email pipelineday@roivant.com.

About Myovant Sciences

Myovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of women's health and endocrine diseases. Myovant's goal is to be the leading global biopharmaceutical company focused on treating women's health and endocrine diseases in areas of high unmet medical need. Myovant's lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a GnRH receptor antagonist. Myovant has 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 (LIBERTY 1 and 2), two in women with endometriosis-associated pain (SPIRIT 1 and 2), and one in men with advanced prostate cancer (HERO). Myovant is also developing MVT-602, a kisspeptin agonist, for the treatment of female infertility as part of assisted reproduction. Takeda Pharmaceuticals International AG has granted Myovant an exclusive, worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries where Takeda retains exclusive rights) and an exclusive license to develop and commercialize MVT-602 in all countries worldwide. Over time, Myovant 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 www.myovant.com.

Forward-Looking Statements
This press release contains forward-looking statements, including without limitation, statements related to: Myovant being on track for top-line results from all relugolix Phase 3 clinical studies during 2019; the statements and Dr. Seely's quotes regarding Myovant's expectations with respect to patient screening, enrollment and anticipated timing for reporting top-line data for Myovant's ongoing global Phase 3 clinical development programs of relugolix for the treatment of heavy menstrual bleeding associated with uterine fibroids, and Myovant's intention to expand its development pipeline to include other potential treatments for women's health and endocrine diseases. Forward-looking statements can be identified by the words "anticipate," "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. Myovant 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. Forward-looking statements 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. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Part I, Item 1A of Myovant's Annual Report on Form 10-K which was filed with the Securities and Exchange Commission on June 7, 2018, and other filings that Myovant makes with the SEC from time to time. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, Myovant undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

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