Myovant Sciences Announces Completion of Enrollment in Phase 3 HERO Trial of Relugolix in Men with Advanced Prostate Cancer

October 24, 2018

- Top-line data expected in fourth quarter of 2019

BASEL, Switzerland, Oct. 24, 2018 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV) today announced it has completed patient enrollment in its pivotal Phase 3 clinical trial, HERO, which is evaluating the safety and efficacy of relugolix for the treatment of men with advanced prostate cancer. The HERO study is designed to support approval by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the Japanese Pharmaceuticals and Medical Devices Agency.

"Completion of enrollment in HERO is a critical milestone for our prostate cancer program," said Lynn Seely, M.D., President and CEO of Myovant. "We look forward to reporting top-line efficacy and safety data for HERO in the fourth quarter of 2019. Relugolix is the only oral gonadotropin-releasing hormone, or GnRH, receptor antagonist in development to lower testosterone and prostate-specific antigen, or PSA, in men with prostate cancer."

Pending positive Phase 3 results, Myovant expects to submit a New Drug Application for relugolix with the FDA in early 2020. If approved, relugolix has the potential to be the first oral GnRH receptor antagonist approved for the treatment of advanced prostate cancer. Relugolix is administered as one pill once-daily and has been shown to decrease testosterone and PSA levels within days in Phase 1 and 2 clinical studies.

About the HERO Study
This randomized, open-label, parallel-group, international Phase 3 clinical trial is evaluating the safety and efficacy of relugolix in men with androgen-sensitive advanced prostate cancer who require at least one year of continuous androgen deprivation therapy. Patients enrolled in the study were randomized 2:1 to receive a single loading dose of relugolix 360 mg followed by relugolix 120 mg once daily or to treatment with leuprolide acetate 3-month depot injection, respectively. The primary efficacy outcome of the study is the ability of relugolix to achieve and maintain serum testosterone suppression to castrate levels (≤50 ng/dL [1.7 nmol/L]) for 48 weeks. A total of 934 patients have been enrolled in the HERO study in North and South America, Europe and the Asia-Pacific region.

About Advanced Prostate Cancer
Prostate cancer is the second most prevalent form of cancer in men and the second leading cause of death due to cancer in men in the United States. According to the National Cancer Institute, approximately 2.9 million men in the United States are currently living with prostate cancer, and approximately 165,000 men are estimated to be newly diagnosed in 2018. Treatment for advanced prostate cancer typically involves treatment with androgen deprivation therapy, which reduces testosterone to very low levels, commonly referred to as castration levels. GnRH agonists, such as leuprolide depot, or slow-release injections are the current standard of care for medical castration. However, GnRH agonists may be associated with mechanism-of-action limitations, including the potentially detrimental initial rise in testosterone levels that can exacerbate clinical symptoms, which is known as clinical or hormonal flare, and delayed testosterone recovery if the drug is discontinued.

About Relugolix
Relugolix is an oral, once-daily, small molecule that acts as a GnRH receptor antagonist. More than 2,150 study participants have received treatment with relugolix, in Phase 1, Phase 2 and Phase 3 clinical trials. In completed trials, relugolix was generally well tolerated and suppressed estrogen and progesterone levels in women and testosterone levels in men. Common side effects observed were consistent with suppression of these hormones.

In the ongoing Phase 3 LIBERTY clinical trials in women with heavy menstrual bleeding associated with uterine fibroids and the ongoing Phase 3 SPIRIT clinical trials in women with endometriosis-associated pain, relugolix is undergoing evaluation alone as monotherapy and in combination with estradiol and norethindrone acetate, a progestin. Myovant is studying whether the combination decreases estradiol levels to the range required to treat signs and symptoms of endometriosis and uterine fibroids while minimizing the side effects associated with low estrogen levels, which include 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-related diseases. 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-1 receptor agonist, that is in Phase 2 development 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: the statements and Dr. Seely's quotes regarding Myovant's expectations with respect to reporting top-line efficacy and safety data for HERO in the fourth quarter of 2019, the timing of submission of an NDA for relugolix with the U.S. Food and Drug Administration in early 2020, the potential of relugolix to be the first oral GnRH antagonist approved for use for the treatment of advanced prostate cancer, and the potential for relugolix to decrease testosterone and prostate-specific antigen within days, control prostate-specific antigen (PSA), and allow for recovery of testosterone in men upon discontinuation. 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 Myovant's Quarterly Report on Form 10-Q which was filed with the Securities and Exchange Commission on August 7, 2018, and other filings that Myovant makes with the SEC from time to time. These statements are based upon information available to Myovant as of the date of this press release, and while Myovant believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and its statements should not be read to indicate that it has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. 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.

Investor Contact:
Frank Karbe
Chief Financial Officer
Myovant Sciences, Inc.
investors@myovant.com

Media Contact:
Julie Normart
W2O pure
jnormart@w2ogroup.com
415.946.108

View original content to download multimedia:http://www.prnewswire.com/news-releases/myovant-sciences-announces-completion-of-enrollment-in-phase-3-hero-trial-of-relugolix-in-men-with-advanced-prostate-cancer-300736738.html

SOURCE Myovant Sciences