Myovant Announces Presentation of Data from Phase 1 Trial of MVT-602 at 2018 American Society for Reproductive Medicine (ASRM) Annual Congress

October 10, 2018

- Administration of a single dose of MVT-602 resulted in dose-related increases in luteinizing hormone concentrations suggesting MVT-602 has potential as a trigger for final egg maturation during in vitro fertilization (IVF)- Treatment with MVT-602 was generally well tolerated in healthy premenopausal women- A Phase 2a study in fertile premenopausal women undergoing controlled ovarian stimulation is ongoing

BASEL, Switzerland, Oct. 10, 2018 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV) today announced the presentation of data from a Phase 1 trial of MVT-602, a novel kisspeptin-1 receptor agonist in development as a potential treatment for female infertility in women as part of assisted reproduction, such as in vitro fertilization (IVF). Results of the study showed that administration of MVT-602 in healthy premenopausal women in the follicular phase produced a dose-related increase in luteinizing hormone concentrations and expected effects on follicle-stimulating hormone and estradiol. The findings were presented during an oral session at the American Society for Reproductive Medicine (ASRM) Annual Congress in Denver.

"We are encouraged by these data, which confirm the potential of MVT-602 to be further studied as an agent that triggers the final maturation of eggs prior to retrieval during controlled ovarian stimulation to treat female infertility," said Lynn Seely, M.D., President and Chief Executive Officer of Myovant Sciences. "Assisted reproduction represents an area of significant need and an exciting new area of focus for Myovant, and we hope to help women with infertility achieve their reproductive goals."

Phase 1 Study Design and Results
The randomized, single-blind, placebo-controlled, parallel group, dose-ranging study was designed to characterize the pharmacokinetics of MVT-602; explore the dose-related changes in luteinizing hormone, follicle-stimulating hormone, estradiol and progesterone; and assess the overall safety and tolerability of MVT-602 in healthy female volunteers. A total of 24 women were randomized to one of three MVT-602 dose groups (0.3 µg, 1 µg or 3 µg) and then subsequently randomized to receive a single subcutaneous dose of MVT-602 or placebo in a 3:1 ratio.

Results showed that administration of single subcutaneous doses of MVT-602 demonstrated dose-related increases in luteinizing hormone concentrations and expected post-dose increases in follicle-stimulating hormone and estradiol concentrations, with little effect observed on progesterone as expected. MVT-602 was absorbed within minutes after subcutaneous administration, with dose-dependent increases in plasma drug exposures and a half-life of less than 3 hours. Further assessment of the exposure-response profile of MVT-602 administered during the pre-ovulatory phase in fertile women undergoing controlled ovarian stimulation is ongoing in a Phase 2a study.

No serious adverse events were reported, and no subject discontinued from the study due to an adverse event. Adverse events were similar between the placebo and MVT-602 groups with no apparent dose-related effects. The observed adverse events were generally mild in severity and included headache, dizziness and abdominal distention.

About MVT-602
MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Kisspeptin is a naturally-occurring peptide that stimulates GnRH release and is required for puberty and maintenance of normal reproductive function, including production of sperm, follicular maturation and ovulation, and production of estrogen and progesterone in women and testosterone in men.

A Phase 2a clinical trial in healthy female volunteers is under way to characterize the dose-response curve in the controlled ovarian stimulation setting prior to studying MVT-602 in infertile women seeking pregnancy.

About Female Infertility and Assisted Reproductive Technology (ART)
Infertility is defined as the inability of a couple to become pregnant after one year of unprotected intercourse in women under age 35 and after six months in women age 35 or older. Infertility affects approximately one in seven couples in western countries and one in four couples in developing countries. About 8 percent of cases of infertility are due to male problems, 37 percent due to female problems, and 35 percent due to problems from both the male and female partners. In about 5 percent of couples, the cause of the infertility cannot be traced to specific problems in either partner.

Approximately 1.6 million ART treatments (including IVF and intracytoplasmic sperm injection) are performed worldwide each year for infertility. The IVF procedure consists of several steps that take place over a period of weeks. Hormonal stimulation of the ovaries is used to produce several eggs, final egg maturation is induced using a trigger agent, and the eggs are subsequently retrieved and fertilized with sperm to allow an embryo to form. One or more of the embryos is transferred into the uterus with the goal of successful implantation and pregnancy. Approximately 27 percent of IVF cycles will end in a live birth, with the cumulative chances of success higher when more than one cycle of IVF is performed. A woman's chance of success depends on her age, cause of infertility, treatment approach and other factors.

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-1 receptor 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: the potential for MVT-602 to be used as a trigger agent during controlled ovarian stimulation; and the statements and Dr. Seely's quote regarding Myovant's expectations with respect to the data on MVT-602. 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 risks are not exhaustive. New risk factors emerge from time to time and it is not possible for its management to predict all risk factors, nor can Myovant assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe," "Myovant believes," and similar statements reflect its beliefs and opinions on the relevant subject. 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. 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.

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

Media Contact:
Julie Normart
W2O pure
jnormart@w2ogroup.com
415.946.1087

View original content to download multimedia:http://www.prnewswire.com/news-releases/myovant-announces-presentation-of-data-from-phase-1-trial-of-mvt-602-at-2018-american-society-for-reproductive-medicine-asrm-annual-congress-300728719.html

SOURCE Myovant Sciences