Myovant Sciences and Pfizer Announce First Participant Dosed in Phase 3 SERENE Study Evaluating Contraceptive Efficacy of Once-Daily Relugolix Combination Tablet

Monday, April 12, 2021 - 07:00am

SERENE is a Phase 3 single-arm, open-label study evaluating the contraceptive efficacy of investigational relugolix combination tablet in sexually active, healthy women ages 18-35 years Contraceptive potential of relugolix combination tablet supported by prior Phase 1 study that demonstrated 100% ovulation inhibition Data would support a potential indication of pregnancy prevention for women treated with relugolix combination tablet, if approved

BASEL, Switzerland and NEW YORK, April 12, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV) and Pfizer Inc. (NYSE: PFE) today announced that the first participant has been dosed in the Phase 3 SERENE study evaluating the contraceptive efficacy of relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) in healthy women ages 18-35 years who are at risk for pregnancy.

"We are committed to redefining care for women, which means supporting their overall health and quality of life. Many women with uterine fibroids and endometriosis need to simultaneously manage their symptoms and their reproductive choices – including prevention of pregnancy," said Juan Camilo Arjona Ferreira, M.D., Chief Medical Officer of Myovant Sciences, Inc. "The Phase 3 SERENE study is designed to assess the potential of relugolix combination tablet to prevent pregnancy, and will complement data from our Phase 3 LIBERTY and SPIRIT programs which demonstrated the promise of relugolix

combination therapy as a potential treatment for uterine fibroids and endometriosis.”

The SERENE study will enroll 900 sexually active, healthy women ages 18-35 years with presumed normal fertility. The primary efficacy endpoint is the at-risk Pearl Index, defined as the number of on-treatment pregnancies per 100 women-years of treatment. On-treatment pregnancies are pregnancies with an estimated conception date between the first day of study intervention intake up to and including seven days after the last intake of study medication. Women will receive once-daily relugolix combination tablet for 13 28-day at-risk cycles. Safety data will also be collected during the study.

“The findings of the Phase 1 study demonstrated that relugolix combination therapy inhibited ovulation in all the study participants and provided the basis for the SERENE study to evaluate whether relugolix combination tablet has the potential to prevent pregnancy in women receiving therapy,” said James Rusnak, M.D., Ph.D., Senior Vice President, Chief Development Officer, Internal Medicine and Hospital, Global Product Development at Pfizer. “The data from this Phase 3 study will provide important information to patients and healthcare providers when making treatment decisions for women with endometriosis and uterine fibroids.”

In April 2020, Myovant announced results from a Phase 1 single-arm, open-label ovulation inhibition study to assess the effects of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) on ovulation inhibition, per the Hoogland-Skouby assessment scale (score < 5). In 67 healthy women over an 84-day treatment period (three cycles), relugolix combination therapy achieved 100% ovulation inhibition and was generally well tolerated. Furthermore, 100% of women resumed ovulation or menses upon discontinuation of treatment, with an average time to ovulation of 23.5 days. Data from this study were previously presented at the American Society for Reproductive Medicine 2020 Virtual Congress. Relugolix combination tablet is under review by the U.S. Food and Drug Administration for the treatment of women with uterine fibroids, with a decision expected by the June 1, 2021 target action date. The submission of a New Drug Application for the treatment of moderate to severe pain associated with endometriosis is anticipated in the first half of 2021.

More information can be found at www.clinicaltrials.gov, identifier: NCT04756037.

About Myovant Sciences Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. We have one FDA-approved medicine, ORGOVYX™ (relugolix), for adult patients with advanced prostate cancer. Our lead product candidate, relugolix

combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), is under regulatory review in Europe and the U.S. for women with uterine fibroids and is under development for women with endometriosis. We are also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for female infertility as part of assisted reproduction. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is our majority shareholder. For more information, please visit our website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer. **Myovant Sciences Forward-Looking Statements** This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In this press release, forward-looking statements include, but are not limited to, all statements and quotes reflecting Myovant Sciences' expectations of the SERENE study, including the timing and quality of the clinical results and any potential indication that may result from any regulatory filing; and the expected timing of Myovant's other regulatory filings and potential approvals. Myovant Sciences' forward-looking statements are based on management's current expectations and beliefs and 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, including the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates, as well as the possibility of

unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether and when the FDA may approve the pending application for relugolix combination tablet for women with uterine fibroids and the potential application for women with endometriosis, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether relugolix will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of relugolix; and unforeseen circumstances or other disruptions to normal business operations arising from or related to the COVID-19 pandemic. Myovant Sciences cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Factors that could materially affect Myovant Sciences' operations and future prospects or which could cause actual results to differ materially from expectations include, but are not limited to, the risks and uncertainties listed in Myovant Sciences' filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Myovant Sciences' Quarterly Report on Form 10-Q filed on February 11, 2021, as such risk factors may be amended, supplemented or superseded from time to time. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for Myovant Sciences' management to predict all risk factors, nor can Myovant Sciences 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. You should not place undue reliance on the forward-looking statements in this press release, which speak only as of the date hereof, and, except as required by law, Myovant Sciences undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements. **Pfizer Disclosure Notice** The information contained in this release is as of April 12, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about relugolix combination tablet for women with uterine fibroids, relugolix combination tablet for women with endometriosis, ORGOVYX (relugolix) for the treatment of adult patients with advanced prostate cancer and a collaboration between Pfizer and Myovant Sciences to develop and commercialize relugolix in advanced prostate cancer and women's health, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and

uncertainties include, among other things, uncertainties regarding the commercial success of relugolix; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when the potential application for relugolix for women with endometriosis will be filed with the FDA and whether and when any applications may be filed for relugolix for advanced prostate cancer, for women with uterine fibroids or for women with endometriosis in additional jurisdictions or in any jurisdictions for any other potential indications for relugolix; whether and when the FDA may approve the pending application for relugolix for women with uterine fibroids and the potential application for women with endometriosis and whether and when regulatory authorities may approve any other applications that may be filed for relugolix in other jurisdictions, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether relugolix will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of relugolix; whether our collaboration with Myovant Sciences will be successful; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

Pfizer Media Contact:

Steve Danehy +1 (212) 733-1538 Steven.Danehy@Pfizer.com

Pfizer Investor Contact:

Chuck Triano +1 (212) 733-3901 Charles.E.Triano@Pfizer.com

Myovant Sciences Media Contact:

Albert Liao +1 (650) 410-3055 media@myovant.com

Myovant Sciences Investor Contact:

Ryan Crowe +1 (650) 781-9106 investors@myovant.com