Pfizer Logo

Myovant Sciences and Pfizer Announce Positive One-Year Data from Phase 3 SPIRIT Extension Study of Once-Daily Relugolix Combination Therapy in Women with Endometriosis

Tuesday, January 26, 2021 - 06:55am

- 84.8% and 73.3% of women reported clinically meaningful reductions in dysmenorrhea (menstrual pain) and non-menstrual pelvic pain at one year
- 82.8% average reduction from baseline on the Numerical Rating Scale for dysmenorrhea from 7.4 (severe pain) to 1.3 (mild pain) over one year
- Bone mineral density loss was minimal at Week 24 and remained stable through one year
- Data to be included in New Drug Application submission to U.S. Food and Drug Administration anticipated in first half of 2021

BASEL, Switzerland and NEW YORK, January 26, 2021 - Myovant Sciences (NYSE: MYOV) and Pfizer Inc. (NYSE: PFE) today announced that the Phase 3 SPIRIT long-term extension study of the investigational once-daily relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with endometriosis reported clinically meaningful reductions in dysmenorrhea (menstrual pain) and non-menstrual pelvic pain over one year (52 weeks) with minimal and stable bone mineral density loss. The data are consistent with the efficacy and safety profile observed through 24 weeks in the Phase 3 SPIRIT 1 and SPIRIT 2 studies. These results will be included in the New Drug Application to the U.S. Food and Drug Administration for relugolix combination tablet for the treatment of women with endometriosis, anticipated to be submitted in the first half of 2021.

“Given the debilitating impact that endometriosis can have on women in their daily lives, often over many years, we need non-invasive and long-term treatment options,” said Linda Giudice, M.D., Ph.D., Distinguished Professor in the Center for Reproductive Sciences at the University of California, San Francisco (UCSF) and SPIRIT Program Steering Committee Member. “The one-year data from the Phase 3 SPIRIT extension study offers promising evidence that relugolix combination therapy has the potential to significantly and durably reduce pain in women with endometriosis, while remaining well tolerated.”

In the SPIRIT long-term extension study, 84.8% and 73.3% of women receiving relugolix combination therapy over one year achieved clinically meaningful pain reductions in dysmenorrhea and non-menstrual pelvic pain, respectively. On average, women reported an 82.8% reduction on the 11-point Numerical Rating Scale (0-10) for dysmenorrhea from 7.4 (severe pain) to 1.3 (mild pain) over one year.

“Building on the strength of our one-year data of relugolix combination therapy in uterine fibroids, we are pleased by the one-year safety and efficacy data in women with endometriosis, which further our vision for a one pill, once-a-day treatment option suitable for long-term use in both diseases,” said Juan Camilo Arjona Ferreira, M.D., Chief Medical Officer of Myovant Sciences, Inc. “We look forward to submitting a New Drug Application for this potential new treatment for women with endometriosis in the first half of this year.”

“Endometriosis is a common and painful condition, which impacts approximately 10 percent of women during their reproductive lifetime,” said James Rusnak, M.D., Ph.D., Senior Vice President, Chief Development Officer, Internal Medicine and Hospital, Global Product Development at Pfizer. “We believe the results from the one-year extension study show the encouraging potential of relugolix combination therapy to evolve the treatment paradigm for women with endometriosis.”

Bone mineral density remained stable through Week 52 in women treated with relugolix combination therapy after minimal, non-clinically meaningful bone loss through Week 24. The incidence of adverse events over one year was consistent with that observed in SPIRIT 1 and SPIRIT 2, with no new safety signals observed. The most commonly reported adverse events in at least 10% of women treated with relugolix combination therapy were headache, nasopharyngitis, and hot flashes. There was one pregnancy reported in the relugolix combination therapy group (n = 278).

Data from SPIRIT 1 and SPIRIT 2 studies were previously presented at the American Society for Reproductive Medicine (ASRM) 2020 Virtual Congress. Complete results from the SPIRIT long-term extension study will be submitted for presentation at a future scientific meeting and publication in a medical journal.

In December 2020, Myovant and Pfizer entered into a collaboration for the development and commercialization of relugolix in oncology and women’s health in the U.S. and Canada. Under the terms of the agreement, Myovant and Pfizer will jointly develop and commercialize ORGOVYXTM (relugolix) in advanced prostate cancer and, if approved, relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) in uterine fibroids and endometriosis.

About the Phase 3 SPIRIT Program in Endometriosis

The Phase 3 clinical program for endometriosis consists of two multinational, replicate pivotal clinical studies (SPIRIT 1 and SPIRIT 2) of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in over 1,200 women with pain associated with endometriosis. Women received treatment either with relugolix combination therapy for 24 weeks, relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix combination therapy once daily for an additional 12 weeks, or placebo once daily for 24 weeks. Eligible women who completed the SPIRIT 1 or SPIRIT 2 studies were offered the opportunity to enroll in an active treatment extension study in which all women receive relugolix combination therapy for an additional 80-week period, resulting in a total treatment period of up to 104 weeks, designed to evaluate the safety and sustained efficacy of longer-term treatment.

About Endometriosis

Endometriosis is an estrogen-dependent, inflammatory 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, requiring a multi-disciplinary approach to care.

For endometriosis-associated pain, per current guidelines, initial treatment options include hormonal contraceptives and over-the-counter pain medications. In more severe cases, LHRH agonists such as leuprolide acetate are used for short-term treatment. An estimated six million women in the U.S. suffer from symptoms of endometriosis, and an estimated one million women are inadequately treated by current medical therapy and require further treatment. Almost 200 million women are affected globally.

About Myovant Sciences

Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Our lead product candidate, relugolix, is a once-daily, oral GnRH receptor antagonist. Relugolix (120 mg) is FDA-approved as ORGOVYX™ for adult patients with advanced prostate cancer. 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, including Myovant Sciences' aspiration to redefine care for women and for men; the expected timing and strength of Myovant's regulatory filings; the potential for relugolix combination therapy to significantly and durably reduce pain in women with endometriosis with a well-tolerated safety profile; the potential for relugolix combination therapy to evolve the treatment paradigm for women with endometriosis; and Myovant's vision for a one pill, once-a-day, treatment option suitable for long-term use in uterine fibroids and endometriosis.

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 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 and actual results could differ materially from those expressed or implied by these forward-looking statements. 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 November 12, 2020, 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 January 26, 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 endometriosis, relugolix combination tablet for women with uterine fibroids, 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 and potential regulatory submission, 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 ORGOVYX; 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 combination tablet 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 or relugolix combination tablet 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 combination tablet 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 or relugolix combination tablet 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 and relugolix combination tablet 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 or relugolix combination tablet; 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, 2019 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 Relations Contact: Ryan Crowe +1 (650) 781-9106 investors@myovant.com