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Myovant Sciences and Pfizer Announce Publication in the New England Journal of Medicine of Phase 3 LIBERTY Studies of Once-Daily Relugolix Combination Therapy in Women with Uterine Fibroids

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BASEL, Switzerland and NEW YORK, February 17, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV) and Pfizer Inc. (NYSE: PFE) today announced publication in the *New England Journal of Medicine* of the Phase 3 LIBERTY 1 and LIBERTY 2 studies of investigational once-daily relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with uterine fibroids. As previously reported, both studies achieved the primary endpoint of response rates in menstrual blood loss in addition to six of the seven key secondary endpoints, while maintaining bone mineral density comparable to placebo as part of a well-tolerated safety profile over 24 weeks.

“Women with uterine fibroids often suffer from symptoms such as heavy menstrual bleeding and pain, which can significantly impact their quality of life over many years,” said Ayman Al-Hendy, M.D., Ph.D., Professor of Obstetrics and Gynecology, University of Chicago, and lead author of the publication. “In the LIBERTY studies, relugolix combination therapy improved the most bothersome symptoms of uterine fibroids and had a well-tolerated safety profile including maintenance of bone mineral density comparable to placebo. The data published in the *New England Journal of Medicine* underscore the potential of relugolix combination therapy to provide an important new treatment option for this common disease.”

LIBERTY 1 and LIBERTY 2 each met the primary endpoint, with 73.4% and 71.2% of women in the relugolix combination therapy groups achieving the responder criteria compared with 18.9% and 14.7% of women in the placebo groups at Week 24, respectively (both $p < 0.001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50% or greater reduction from baseline in menstrual blood loss volume during the last 35 days of treatment measured using the alkaline hematin method. On average, women receiving relugolix combination therapy experienced an 84.3% reduction in menstrual blood loss from baseline in each study (both $p < 0.001$ compared to placebo).

“We are pleased that the *New England Journal of Medicine* recognized the importance of our Phase 3 LIBERTY program and published the study results, which support the potential of once-daily relugolix combination therapy in women with uterine fibroids,” said Juan Camilo Arjona Ferreira, M.D., Chief Medical Officer of Myovant Sciences, Inc. “As we approach our FDA target action date of June 1, we look forward, if approved, to providing a one pill, once-a-day treatment for the millions of women with uterine fibroids who need and deserve new options.”

In LIBERTY 1 and LIBERTY 2, six of seven key secondary endpoints measured at Week 24 achieved statistical significance, including mean reduction in menstrual blood loss, amenorrhea, reduction in pain in women with pain at baseline, improvement on the Bleeding and Pelvic Discomfort scale, reduction in uterine volume (all $p < 0.001$ compared to placebo), and improvement in anemia in those women with anemia at baseline (both $p < 0.05$ compared to placebo). In addition, among the approximately 50% of women with moderate-to-severe pain at baseline, a significantly greater proportion of women receiving relugolix combination therapy reported minimal-to-no pain (maximum score of 1 on a 0 to 10 Numerical Rating Scale) during the last 35 days of treatment compared to placebo (43% vs. 10% and 47% vs. 17%, respectively; both $p < 0.001$). A seventh key secondary endpoint for reduction in fibroid volume was not achieved in either study.

Data showed changes in bone mineral density were comparable between the relugolix combination and placebo groups at the end of treatment in LIBERTY 1 and LIBERTY 2. The overall incidence of adverse events in the relugolix combination and placebo groups were also comparable (62% vs. 66% and 60% vs. 59%, respectively), including hot flashes (11% vs. 8% and 6% vs. 4%, respectively). There were no pregnancies reported in the relugolix combination groups in either study.

“The heavy bleeding and pain that women with uterine fibroids commonly experience can have a significant impact on their everyday lives,” said James Rusnak, M.D., Ph.D., Senior Vice President, Chief Development Officer, Internal Medicine and Hospital, Global Product Development at Pfizer. “These data offer strong evidence that relugolix combination therapy, if approved, could be an important new oral treatment with the potential to help patients living with this debilitating condition.”

Data from LIBERTY 1 and LIBERTY 2, in addition to the 28-week long-term extension study, were included in the New Drug Application (NDA) for relugolix combination tablet for uterine fibroids, with the FDA decision expected by the June 1, 2021 target action date. Myovant previously announced results from the LIBERTY long-term extension study in February 2020. At one year, 87.7% of women receiving relugolix combination therapy met the responder criteria. In addition, women experienced, on average, an 89.9% reduction in menstrual blood loss from baseline at one year. Changes in bone mineral density and the incidence of adverse events were consistent with those in LIBERTY 1 and LIBERTY 2.

About Uterine Fibroids

Uterine fibroids are noncancerous tumors that develop in or on the muscular walls of the uterus and are among the most common reproductive tract tumors in women. In addition to an individual's genetic predisposition, estrogens are well known to play an important role in the regulation of fibroid growth.

Although uterine fibroids are benign tumors, they can cause debilitating symptoms such as heavy menstrual bleeding (frequently resulting in anemia and fatigue), pain (including painful periods, abdominal pain, painful intercourse, backache), increased abdominal girth and bloating, urinary frequency or retention, constipation, pregnancy loss, and, in some cases, infertility. These symptoms can also lead to loss of productivity at work, limitations in normal activities of daily living, and social embarrassment.

An estimated five million women in the U.S. suffer from symptoms of uterine fibroids, and an estimated three million women are inadequately treated by current medical therapy and require further treatment.

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^{TM} (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 0.5mg), 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; Drs. Al-Hendy, Arjona Ferreira and Rusnak's quotes regarding the potential for relugolix combination tablet for uterine fibroids; the expected timing and strength of Myovant's regulatory filings; and Myovant's vision for a one pill, once-a-day, treatment option suitable for long-term use in uterine fibroids.

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, the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities and whether regulatory authorities will be satisfied with the design of and results from the clinical studies. 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 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 February 17, 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, including a potential indication for women with uterine fibroids, 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 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 any applications may be filed for relugolix for advanced prostate cancer or relugolix combination tablet for women with uterine fibroids in any other jurisdictions or for women with endometriosis or any other potential indications in any jurisdictions; whether and when the FDA may approve the pending application for relugolix combination tablet for women with uterine fibroids and whether and when regulatory authorities may approve any other applications that may be filed for relugolix or relugolix combination tablet in any 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.

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