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Myovant Sciences and Pfizer Announce Positive Data from Phase 3 LIBERTY Randomized Withdrawal Study of Once-Daily Relugolix Combination Therapy in Women with Uterine Fibroids

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- ***78.4% of women who continued on relugolix combination therapy remained responders (menstrual blood loss < 80 mL) through Week 76 compared with 15.1% of women who discontinued treatment at Week 52 (p < 0.0001)***
- ***69.8% of women who continued relugolix combination therapy remained responders through Week 104***
- ***88.3% of women who discontinued treatment relapsed with heavy menstrual bleeding, on average 5.9 weeks after discontinuation***
- ***Myovant to host conference call and webcast today at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time***

BASEL, Switzerland and NEW YORK, March 24, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV) and Pfizer Inc. (NYSE: PFE) today announced positive data from the Phase 3 LIBERTY randomized withdrawal study of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with uterine fibroids. This study was designed to assess the safety and efficacy of continued treatment with relugolix combination therapy for up to two years.

“Since many women with uterine fibroids spend years struggling to manage their symptoms, there is a critical need for non-invasive long-term treatment options,” said Ayman Al-Hendy, M.D., Ph.D., Professor of Obstetrics and Gynecology, University of Chicago and LIBERTY Program Steering Committee Member. “Data from the LIBERTY randomized withdrawal study demonstrate the potential value of continued treatment for women with uterine fibroids, with those receiving relugolix combination therapy in the study experiencing meaningful symptom relief for up to two years.”

The LIBERTY randomized withdrawal study (N = 229) was a Phase 3 double-blind, placebo-controlled study that enrolled eligible women who completed the LIBERTY long-term extension study. Eligibility criteria included meeting the responder criteria at one year. Responder criteria were 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. Women were randomized at Week 52 to once-daily relugolix combination therapy or placebo for a one-year double-blind treatment period. Women on placebo with relapse of heavy menstrual bleeding during the study were offered re-treatment with open-label relugolix combination therapy. This study, together with the LIBERTY 1, LIBERTY 2, and LIBERTY long-term extension studies, was designed to provide data on the safety and efficacy of treatment with relugolix combination therapy for up to two years.

“We are pleased to see the positive data from the LIBERTY randomized withdrawal study which support the potential benefit of longer-term treatment with relugolix combination therapy,” said Juan Camilo Arjona Ferreira, M.D., Chief Medical Officer of Myovant Sciences, Inc. “We look forward to making the full data available at a future medical congress.”

“Uterine fibroids can affect many women during their lifetime with uncomfortable symptoms, such as heavy menstrual bleeding,” said James Rusnak, M.D., Ph.D., Senior Vice President, Chief Development Officer, Internal Medicine and Hospital, Global Product Development at Pfizer. “We believe that these study results offer encouraging data in support of longer-term efficacy in women suffering from uterine fibroids.”

The LIBERTY randomized withdrawal study met its primary endpoint with 78.4% of women who continued on relugolix combination therapy achieving the sustained responder rate (menstrual blood loss < 80 mL) through Week 76 compared with 15.1% of women who discontinued treatment and initiated placebo at Week 52 ($p < 0.0001$). All three key secondary endpoints in the LIBERTY randomized withdrawal study were also achieved, including sustained responder rate at two years (Week 104), time to relapse of heavy menstrual bleeding, and amenorrhea rate (all $p < 0.0001$). Through two years, 69.8% of women who continued on relugolix combination therapy remained responders. 88.3% of women who discontinued treatment at Week 52 relapsed with heavy menstrual bleeding, with a median time of return to heavy menstrual bleeding of 5.9 weeks.

Bone mineral density was maintained through two years in the subset of women continuously treated with relugolix combination therapy (N = 31). The incidence of adverse events over one additional year of treatment was consistent with those observed in prior studies, with no new safety signals observed. The most commonly reported adverse event in at least 10% of women treated with relugolix combination therapy was nasopharyngitis.

Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under review by the U.S. Food and Drug Administration (FDA) for the treatment of women with uterine fibroids, with a decision expected by the June 1, 2021 target action date.

Myovant Sciences Conference Call

Myovant will hold a webcast and conference call at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time today, March 24, 2021. Investors and the general public may access a live webcast of the call by visiting the investor relations page of Myovant’s website at investors.myovant.com. Institutional investors and analysts may also participate in the conference call by dialing 1-800-532-3746 in the U.S. or +1-470-495-9166 from outside the U.S.

The webcast will be archived on Myovant’s Investor Relations website following the call.

About the Phase 3 LIBERTY Program in Uterine Fibroids

The Phase 3 clinical program for uterine fibroids consisted of two multinational, replicate pivotal clinical studies (LIBERTY 1 and LIBERTY 2) of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with heavy menstrual bleeding associated with uterine fibroids for 24 weeks. Eligible women who completed the LIBERTY 1 or LIBERTY 2 studies were offered the opportunity to enroll in an active treatment extension study in which all women received relugolix combination therapy for an additional 28-week period for a total treatment period of 52 weeks, designed to evaluate the safety and efficacy of longer-term treatment. Upon completion of this 52-week total treatment period, eligible women could elect to participate in a second 52-week randomized withdrawal study designed to provide two-year safety and efficacy data on relugolix combination therapy and to evaluate the need for maintenance therapy. Across studies, 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.

LIBERTY 1 and 2 met their primary endpoints ($p < 0.0001$) with 73.4% and 71.2% of women receiving relugolix combination therapy achieving the responder criteria compared with 18.9% and 14.7% of women receiving placebo at 24 weeks, respectively. On average, women receiving relugolix combination therapy in both studies experienced an 84.3% reduction in menstrual blood loss from baseline at Week 24 ($p < 0.0001$). Bone mineral density was comparable between the relugolix combination therapy and placebo groups in LIBERTY 1 and 2. The distribution of the change in bone mineral density, including outliers, was similar for the relugolix combination therapy and placebo groups at 24 weeks, as assessed by dual energy x-ray absorptiometry (DXA). The overall incidence of adverse events in the relugolix combination and placebo groups was comparable in both studies.

The open-label extension study also met its primary endpoint with relugolix combination therapy demonstrating an 87.7% response rate at one year, showing the durability of the response observed in LIBERTY 1 and 2. In addition, women experienced, on average, an 89.9% reduction in menstrual blood loss from baseline at Week 52. Changes in bone mineral density through one year, as assessed by DXA every three months, were consistent with LIBERTY 1 and 2. The incidence of adverse events over one year was consistent with that observed in LIBERTY 1 and 2, with no new safety signals observed.

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 170 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; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; 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 combination tablet in any jurisdictions, which will depend on myriad factors, including making a determination as to whether the investigational product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether 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 combination tablet; and whether our collaboration with Pfizer will be successful. 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 March 24, 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 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 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 or 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, 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.

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