Pfizer Logo

Myovant Sciences and Pfizer Announce Collaboration to Develop and Commercialize Relugolix in Oncology and Women's Health

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BASEL, Switzerland and NEW YORK, Dec. 28, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV) and Pfizer Inc. (NYSE: PFE) today announced a collaboration to develop and commercialize relugolix – a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist – in oncology and women's health in the U.S. and Canada. Pfizer will also receive an exclusive option to commercialize relugolix in oncology outside the U.S. and Canada, excluding certain Asian countries.

"We are thrilled to partner with Pfizer to unlock the full potential of ORGOVYX in advanced prostate cancer and relugolix combination tablet in uterine fibroids and endometriosis, advancing our mission to redefine care for women and for men," said Lynn Seely, M.D., Chief Executive Officer, Myovant Sciences, Inc. "Pfizer is the ideal partner for Myovant given its impressive capabilities and track record across both oncology and women's health. This transformative collaboration will significantly strengthen the upcoming launch of ORGOVYX and the potential launches of relugolix combination tablet in women's health, while substantially enhancing our financial position and enabling us to expand our pipeline of potential new medicines."

Under the terms of the agreement, Myovant and Pfizer will jointly develop and commercialize ORGOVYX™ (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 women's health in the U.S. and Canada. Myovant and Pfizer will begin co-promoting ORGOVYX for advanced prostate cancer in early 2021. Myovant and Pfizer will equally share profits and certain expenses for ORGOVYX and relugolix combination tablet with Myovant recording revenues. Myovant will remain responsible for regulatory interactions and drug supply and continue to lead clinical development for relugolix combination tablet. Myovant will receive up to $4.2 billion, including an upfront payment of $650 million, $200 million in potential regulatory milestones for U.S. Food and Drug Administration (FDA) approvals for relugolix combination tablet in women's health, and tiered sales milestones upon reaching certain thresholds up to $2.5 billion in net sales for prostate cancer and also for the combined women's health indications. If Pfizer exercises the option to commercialize relugolix in oncology outside of the U.S. and Canada, excluding certain Asian countries, Myovant will receive $50 million and be entitled to receive double-digit royalties on sales.

"We are excited to join forces with Myovant and combine our capabilities to bring ORGOVYX to patients with advanced prostate cancer," said Andy Schmeltz, Global President, Pfizer Oncology. "This strategic collaboration builds on our leadership in serving prostate cancer patients in the U.S. and aligns with our goal to deliver more breakthroughs across the prostate cancer treatment paradigm."

“There continues to be a high unmet need among the millions of women who experience the common and debilitating symptoms associated with uterine fibroids and endometriosis,” said Nick Lagunowich, Global President, Pfizer Internal Medicine. “We believe our deep heritage and leadership in women’s health combined with our experienced women’s health field force will enable us to maximize these opportunities with Myovant, potentially bringing valuable new treatment options to these women.”

The FDA approved ORGOVYX on December 18, 2020 for the treatment of adult patients with advanced prostate cancer. ORGOVYX is the first and only oral GnRH antagonist for men with advanced prostate cancer. Relugolix combination tablet is currently under regulatory review by the FDA for women with uterine fibroids, with a target action date of June 1, 2021. Relugolix combination tablet is also under development for women with endometriosis, with a New Drug Application submission anticipated in the first half of 2021.

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, December 28, 2020. 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 Relugolix
Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces testicular testosterone, a hormone known to stimulate the growth of prostate cancer, and ovarian estradiol, a hormone known to stimulate the growth of uterine fibroids and endometriosis. 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.

About ORGOVYX™ (relugolix)
ORGOVYX (relugolix) is the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist approved by the FDA for the treatment of adult patients with advanced prostate cancer. As a GnRH antagonist, ORGOVYX blocks the GnRH receptor and reduces production of testicular testosterone, a hormone known to stimulate the growth of prostate cancer.

For full prescribing information, including patient information, please click here.

Indication

ORGOVYX is approved for the treatment of adult patients with advanced prostate cancer.

Select Important Safety Information

Androgen deprivation therapy, such as ORGOVYX, may **prolong the QT/QTc interval**. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, or frequent electrolyte abnormalities and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.

The safety and efficacy of ORGOVYX have not been established in females. Based on findings in animals and mechanism of action, ORGOVYX can cause **fetal harm and loss of pregnancy** when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the last dose of ORGOVYX.

Most common adverse reactions (? 10%) in patients receiving ORGOVYX were hot flush (54%), musculoskeletal pain (30%), fatigue (26%), constipation (12%), and diarrhea (12%).

Most common laboratory abnormalities (? 15%) in patients receiving ORGOVYX were glucose increased (44%), triglycerides increased (35%), hemoglobin decreased (28%), alanine aminotransferase increased (27%), and aspartate aminotransferase increased (18%).

Co-administration of ORGOVYX with a P-gp inhibitor increases the area under the curve (AUC) and maximum concentration (Cmax) of ORGOVYX, which may increase the risk of adverse reactions associated with ORGOVYX. Avoid co-administration of ORGOVYX with oral P-gp inhibitors. If co-administration is unavoidable, take ORGOVYX first, separate dosing by at least 6 hours, and monitor patients more frequently for adverse reactions.

Co-administration of ORGOVYX with a combined P-gp and strong CYP3A inducer decreases the AUC and Cmax of ORGOVYX, which may reduce the effects of ORGOVYX. Avoid co-administration of ORGOVYX with combined P-gp and strong CYP3A inducers. If co-administration is unavoidable, increase the ORGOVYX dose to 240 mg once daily.

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 Statement
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; Myovant's expectations regarding the potential benefits of ORGOVYX and of other relugolix product candidates; the potential benefits of the collaboration with Pfizer, including Myovant Sciences' upcoming and potential commercial launches, its financial position and potential expansion of new medicine pipeline; the timing and anticipated actions under the agreement and on Myovant Sciences' regulatory filings.

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's dependence on the success of ORGOVYX and its other product candidates; Myovant's ability to sustain a commercial field organization and distribution network; the degree of acceptance of ORGOVYX among physicians, patients, healthcare payors, patient advocacy groups, and the general medical community; Myovant's ability to obtain favorable coverage and reimbursement from third-party payors for ORGOVYX and its other product candidates; and Myovant's reliance on third parties for the manufacture of ORGOVYX and its other product candidates. 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 December 28, 2020. 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 ORGOVYX (relugolix) for the treatment of adult patients with advanced prostate cancer, relugolix combination tablet for women with uterine fibroids, relugolix combination tablet for women with endometriosis 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 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, 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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