

Sumitovant Biopharma Announces Myovant Sciences and Pfizer Enter Collaboration to Develop and Commercialize Relugolix in Oncology and Women's Health

- Myovant and Pfizer to jointly develop and commercialize ORGOVYXTM (relugolix) and relugolix combination tablet and share profits and expenses in the U.S. and Canada
 - Myovant to receive an upfront payment of \$650 million in addition to potential regulatory and sales milestones for a total payment of up to \$4.2 billion
 - ORGOVYX (relugolix) is the first approved therapy in the Sumitovant Biopharma family of companies
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NEW YORK and LONDON, Dec. 28, 2020 (GLOBE NEWSWIRE) — Sumitovant Biopharma Ltd., the majority shareholder of Myovant Sciences (NYSE: MYOV), announced today that Myovant Sciences, a healthcare company focused on redefining care for women and for men, and one of the five healthcare companies in the Sumitovant family of companies, and Pfizer Inc. (NYSE: PFE) have formed 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 have been anticipating and planning for the commercial launch of the first product in our family of companies", said Myrtle Potter, Chief Executive Officer of Sumitovant Biopharma. "With the approval of ORGOVYX, we are now realizing that goal and have taken steps to position ORGOVYX for success by supporting Myovant in forming an empowering collaboration between Myovant Sciences and Pfizer."

"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 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 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.

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 potentially anticipated in the first half of 2021.

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 ORGOVYXTM 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 ORGOVYXTM (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 ORGOVYXTM 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 Sumitovant Biopharma Ltd.

Sumitovant is a global biopharmaceutical company with offices in New York City and London. Sumitovant is a wholly owned subsidiary of Sumitomo Dainippon Pharma. Sumitovant is the majority shareholder of Myovant Sciences and Urovant Sciences, and wholly owns Enzyvant Therapeutics, Spirovant Sciences, and Altavant Sciences. Sumitovant's promising pipeline is comprised of early-through late-stage investigational medicines across a range of disease areas targeting high unmet need. For further information about Sumitovant, please visit <https://www.sumitovant.com>.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China, and the European Union. Sumitomo Dainippon Pharma is based on the 2005 merger between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has more than 6,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at <https://www.ds-pharma.com>.

Sumitovant Biopharma and 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 Sumitovant's and 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.

Sumitovant's and 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. Sumitovant and 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 Sumitovant's or Myovant Sciences' management to predict all risk factors, nor can Sumitovant or 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, neither Sumitovant nor Myovant Sciences undertakes any obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

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[Pfizer-Enter-Collaboration-to-Develop-and-Commercialize-Relugolix-in-Oncology-and-Womens-Health](#)