Myovant Sciences Announces U.S. Availability of ORGOVYX™ for the Treatment of Advanced Prostate Cancer

January 5, 2021

BASEL, Switzerland, Jan. 05, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced that ORGOVYX™ (relugolix), the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with advanced prostate cancer, is now available through authorized specialty distributors.

“Myovant has been focused on ensuring access to ORGOVYX for men with advanced prostate cancer as quickly as possible following approval, and we are delighted to announce that it is now available,” said David Marek, chief executive officer of Myovant Sciences, Inc. “As part of our commitment to redefine care for women and for men, this is a critical step as we work to bring about a new standard of care for men with advanced prostate cancer.”

ORGOVYX was approved by the FDA on December 18, 2020. Myovant is committed to ensuring that men in the U.S. who are prescribed ORGOVYX can achieve fair and timely access and receive the support they may need throughout their treatment journey. As part of this commitment, Myovant has launched the ORGOVYX Support Program which provides insurance verifications, prior authorizations, copay support for commercially-insured patients, free trial for up to two months of therapy, and patient assistance for qualifying uninsured patients. For more information, please contact 833-ORGOVYX (833-674-6899), 8 a.m.–8 p.m. Eastern Time, Monday–Friday.

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 (C_{max}) 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 C_{max} 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.

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; Myovant's expectations regarding the potential benefits of ORGOVYX; patient and provider reaction to ORGOVYX; Myovant's goal of establishing ORGOVYX as the new standard of care in advanced prostate cancer; Myovant's patient assistance program for patients; and the features of such patient assistance program, including insurance verifications, prior authorizations, copay support for commercially-insured patients, free trial for up to 2 months of therapy, and patient assistance for qualifying uninsured patients.

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; 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 Myovant's reliance on third parties for the manufacture of ORGOVYX. 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.

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