Myovant Sciences Announces FDA Approval of ORGOVYX™ (relugolix), the First and Only Oral Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist for Advanced Prostate Cancer

December 18, 2020

- *ORGOVYX demonstrated a 96.7% response rate in testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks in the Phase 3 HERO study*
- *Conference call and webcast to be held on December 21 at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time*

BASEL, Switzerland, Dec. 18, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced that the U.S. Food and Drug Administration (FDA) has approved ORGOVYX™ (relugolix) for the treatment of adult patients with advanced prostate cancer. ORGOVYX, which was granted Priority Review by the FDA, is the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist for men with advanced prostate cancer. The approval is based on efficacy and safety data from the Phase 3 HERO study of ORGOVYX in men with advanced prostate cancer. ORGOVYX is expected to be available in January 2021.

Multimedia components are available with this press release here.

“I am enormously pleased by the approval of ORGOVYX and believe it has the potential to usher in a new standard of care for men with prostate cancer requiring androgen deprivation therapy,” said Neal Shore, M.D., medical director of the Carolina Urologic Research Center and HERO program steering committee member. “For the first time, we now have a once-daily oral treatment that effectively and rapidly suppresses testosterone, with a safety analysis showing a lower incidence of major adverse cardiovascular events compared to leuprolide injections, the current standard of care, as evaluated in the Phase 3 HERO study. The COVID-19 pandemic has heightened the importance of oral treatments as men with prostate cancer continue to experience difficulties and risks traveling to receive injections.”

“Prostate cancer is a very personal journey, but a universal truth is that those of us living with this disease want better treatments and options. That is why the approval of ORGOVYX is such an exciting milestone that brings a long-awaited oral treatment option to men with advanced prostate cancer,” said Thomas Farrington, president and founder of the Prostate Health Education Network. “It is so important for men to speak with their doctor and explore what treatment is right for them as they focus on their overall health.”

“With the approval of ORGOVYX, men with advanced prostate cancer now have a new oral treatment option that has demonstrated robust efficacy and safety, all with one pill taken once-a-day,” said Lynn Seely, M.D., chief executive officer of Myovant Sciences, Inc. “We have successfully built our commercial capabilities to bring this newly approved treatment to the urologists and oncologists who care for men with advanced prostate cancer, with the goal of establishing ORGOVYX as the new standard of care. We are incredibly grateful to the men and investigators who participated in the HERO study and to the FDA for expediting the review and approval of ORGOVYX through its Priority Review pathway.”

In the Phase 3 HERO study, ORGOVYX met the primary endpoint and achieved sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks in 96.7% (95% confidence interval [CI]: 94.9-97.9) of men, compared with 88.8% (95% CI: 84.6-91.8) of men receiving leuprolide acetate injections, the current standard of care. ORGOVYX also achieved several key secondary endpoints compared to leuprolide acetate, including suppression of testosterone to castrate levels at Day 4 and Day 15 (56% versus 0% and 99% versus 12%, respectively) and profound suppression of testosterone (< 20 ng/dL) at Day 15 (78% versus 1%). ORGOVYX lowered prostate-specific antigen (PSA), on average, by 65% at Day 15 and by 83% at Day 29. In a substudy, 55% of men treated with ORGOVYX achieved normal testosterone levels (> 280 ng/dL) or returned to baseline within 90 days of treatment discontinuation. The most frequent adverse events reported in at least 10% of men in the ORGOVYX group were hot flush, musculoskeletal pain, fatigue, constipation, and mild to moderate diarrhea. The HERO data were previously presented in an oral presentation at the 2020 American Society of Clinical Oncology (ASCO) Virtual Scientific Program, with simultaneous publication in the *New England Journal of Medicine*.

Myovant is committed to ensuring that men in the U.S. who are prescribed ORGOVYX can obtain access and receive the support they may need throughout their treatment journey. As part of this commitment, Myovant is launching the ORGOVYX Patient 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.

Conference Call and Webcast
Myovant will hold a conference call on December 21, 2020 at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time to discuss the FDA approval of ORGOVYX™ for men with advanced prostate cancer. 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. 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. A replay of the webcast will be archived on Myovant’s investor relations website.

About Prostate Cancer
Prostate cancer is the second most prevalent form of cancer in men and the second leading cause of death due to cancer in men in the U.S. Cardiovascular mortality is the leading cause of death in men with prostate cancer and accounts for 34% of deaths in men with prostate cancer in the U.S. More than three million men diagnosed with prostate cancer are alive in the U.S., and approximately 190,000 men are estimated to be newly diagnosed in 2020.

Prostate cancer is considered advanced when it has spread or come back after initial treatment and may include biochemical recurrence (rising prostate-specific antigen in the absence of metastatic disease on imaging), locally advanced disease, or metastatic disease. Front-line medical therapy for advanced prostate cancer typically involves androgen deprivation therapy, which reduces testosterone to very low levels, commonly

referred to as castrate levels (< 50 ng/dL). Luteinizing hormone-releasing hormone (LHRH) receptor agonists, such as leuprolide acetate, are depot injections and the current standard of care for androgen deprivation therapy. However, LHRH receptor agonists may be associated with mechanism-of-action limitations, including the potentially detrimental initial surge in testosterone levels that can exacerbate clinical symptoms, which is known as clinical or hormonal flare, and delayed testosterone recovery after the drug is discontinued. Approximately 300,000 men are treated with androgen deprivation therapy each year.

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; Myovant's expectation that ORGOVYX will become available in January 2021; Myovant's expectations regarding the potential commercial launch of ORGOVYX in the United States, including launch timing; Myovant's goal of establishing ORGOVYX as the new standard of care in advanced prostate cancer; Myovant's plans to offer a 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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