Myovant Sciences Initiates Phase 3 Clinical Trial of Relugolix in Men with Advanced Prostate Cancer

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BASEL, Switzerland, March 1, 2017 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV) today announced it has initiated a Phase 3 clinical trial, HERO, to evaluate the safety and efficacy of relugolix in treating men with advanced prostate cancer. Relugolix is an oral, once-daily, small molecule, gonadotropin-releasing hormone (GnRH) receptor antagonist that lowers testosterone by inhibiting pituitary release of luteinizing hormone and follicle-stimulating hormone.

"Lowering testosterone levels is oftentimes essential for men with advanced prostate cancer," said Neal Shore, MD, Director of the Carolina Urologic Research Center, Myrtle Beach, SC. "The current therapies used to lower testosterone require injections and the most commonly used GnRH agonists initially raise testosterone and may cause a clinical flare of symptoms. A once-daily oral GnRH antagonist, which both decreases testosterone within days of initiation and has the potential to allow a rapid return of testosterone when discontinued, could offer an advantage to men with advanced prostate cancer, particularly those initiating androgen deprivation therapy and those considering intermittent therapy."

"Our hope is that relugolix will be able to provide the therapeutic benefits of direct testosterone suppression with a GnRH antagonist coupled with the convenience of a once-a-day pill," said Dr. Lynn Seely, MD, President & Chief Executive Officer of Myovant Sciences, Inc. "This international clinical trial designed to gain approval in the United States, Europe, and Asia will be the critical test to achieve that objective."

About the HERO Study
The HERO study is a randomized, open-label, parallel-group Phase 3 international clinical trial to evaluate the safety and efficacy of relugolix in men with androgen-sensitive advanced prostate cancer who require at least one year of continuous androgen deprivation therapy. Approximately 1,125 patients will be enrolled in this study in North and South America, Europe, and the Asia-Pacific region.

Patients enrolled in the study will be randomized 2:1 to receive oral relugolix 120 mg once daily or leuprolide acetate 3-month depot injection, respectively.

The primary efficacy outcome of the study will be the ability of relugolix to achieve and maintain serum testosterone suppression to castrate levels (≤ 50 ng/dL [1.7 nmol/L]) for 48 weeks in patients with androgen-sensitive advanced prostate cancer.

About Advanced 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 United States. According to the National Cancer Institute, approximately 2.9 million men are currently living with prostate cancer in the United States, and approximately 180,000 men are newly diagnosed in the United States each year. Treatment for advanced prostate cancer typically involves treatment with androgen deprivation therapy, which reduces testosterone to very low levels, commonly referred to as castration levels. GnRH agonists, such as leuprolide depot, or slow-release, injections, are the current standard of care for medical castration, causing long-term desensitization and down-regulation of the GnRH-axis. GnRH agonists may be associated with mechanism-of-action limitations, including the potentially detrimental initial rise in testosterone levels that can exacerbate clinical symptoms, which is known as clinical or hormonal flare.

About Relugolix
Relugolix is an oral, once-daily small molecule that acts as a GnRH receptor antagonist and has been evaluated in over 1,300 study participants in Phase 1 and multiple large controlled Phase 2 clinical trials. In these trials, relugolix has been shown to be generally well tolerated and to suppress testosterone levels in men and estrogen and progesterone levels in women. Common side effects are consistent with the lowering of testosterone in men and estrogen and progesterone in women.

About Myovant Sciences
Myovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health and other endocrine-related disorders. Myovant's lead product candidate is relugolix, an oral, once-daily small molecule that acts as a GnRH receptor antagonist. In addition to the HERO study in men with advanced prostate cancer, Myovant has initiated a Phase 3 clinical program for relugolix in women with uterine fibroids and plans to initiate an additional Phase 3 clinical program for relugolix in women with endometriosis-associated pain in the first half of 2017. Myovant is simultaneously developing MVT-602, an analog of kisspeptin, for the treatment of female infertility as part of assisted reproduction. Over time the company intends to expand its development pipeline to include other potential treatments for women's health and endocrine-related disorders. For more information, please visit the company's website at myovant.com.

Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding Myovant's plans to advance the clinical development of its product candidates and expand its development pipeline. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with the success, cost, and timing of the company's product development activities and clinical trials. For further information regarding risks

and uncertainties that could cause actual results to differ from those anticipated by these forward-looking statements, as well as risks relating to Myovant's business in general, see the "Risk Factors" section of Myovant's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on February 13, 2017, and other filings that Myovant makes with the SEC from time to time. These forward-looking statements are based on information available to Myovant as of the date of this press release and speak only as of the date of this release. Myovant disclaims any obligation to update these forward-looking statements, except as may be required by law.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/myovant-sciences-initiates-phase-3-clinical-trial-of-relugolix-in-men-with-advanced-prostate-cancer-300416385.html

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