Sumitovant Biopharma Announces Publication in the New England Journal of Medicine of Myovant Sciences Phase 3 LIBERTY Studies of Once-Daily Relugolix Combination Therapy in Women with Uterine Fibroids

•LIBERTY 1 and LIBERTY 2 achieved 73.4% and 71.2% response rates in menstrual blood loss, with an average reduction of 84.3% from baseline

•Achieved six of seven key secondary endpoints including reduction of pain

•Bone mineral density maintained at levels comparable to placebo

•Data were included in U.S. New Drug Application for relugolix combination tablet for uterine fibroids

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NEW YORK, LONDON, February 17, 2021 (GLOBE NEWSWIRE) — Sumitovant Biopharma Ltd., a majority shareholder of Myovant Sciences (NYSE: MYOV), announced today that the *New England Journal of Medicine* published Myovant Sciences' Phase 3 LIBERTY 1 and LIBERTY 2 studies of investigational once-daily relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with uterine fibroids. As previously reported, both studies achieved the primary endpoint of response rates in menstrual blood loss in addition to six of the seven key secondary endpoints, while maintaining bone mineral density comparable to placebo as part of a well-tolerated safety profile over 24 weeks.

"Peer-reviewed publication of these two important studies in the *New England Journal of Medicine* is a significant step forward for women who suffer from uterine fibroids, said Myrtle Potter, chief executive officer of Sumitovant Biopharma. "The results offer hope for a better quality of life and further the mission of Sumitovant Biopharma to develop therapies that make a difference in patients' lives".

LIBERTY 1 and LIBERTY 2 each met the primary endpoint, with 73.4% and 71.2% of women in the relugolix combination therapy groups achieving the responder criteria compared with 18.9% and 14.7% of women in placebo groups at Week 24, respectively (both $p < 0.001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50% or greater reduction from baseline in menstrual blood loss volume during the last 35 days of treatment measured using the alkaline hematin method. On average, women receiving relugolix combination therapy experienced an 84.3% reduction in menstrual blood loss from baseline in each study (both $p < 0.001$ compared to placebo).

"We are pleased that the *New England Journal of Medicine* recognized the importance of our Phase 3 LIBERTY program and published the study results, which support the potential of once-daily relugolix combination therapy in women with uterine fibroids," said Juan Camilo Arjona Ferreira, M.D., Chief Medical Officer of Myovant Sciences, Inc. "As we approach our FDA target action date of June 1, we look forward, if approved, to providing a one pill, once-a-day treatment for the millions of women with uterine fibroids who need and deserve new options."

In LIBERTY 1 and LIBERTY 2, six of seven key secondary endpoints measured at Week 24 achieved statistical significance, including mean reduction in menstrual blood loss, amenorrhea, reduction in pain in women with pain at baseline, improvement on the Bleeding and Pelvic Discomfort scale, reduction in uterine volume (all $p < 0.001$ compared to placebo), and improvement in anemia in those women with anemia at baseline (both $p < 0.05$ compared to placebo). In addition, among the approximately 50% of women with moderate-to-severe pain at baseline, a significantly greater proportion of women receiving relugolix combination therapy reported minimal-to-no pain (maximum score of 1 on a 0 to 10 Numerical Rating Scale) during the last 35 days of treatment compared to placebo (43% vs. 10% and 47% vs. 17%, respectively; both $p < 0.001$). A seventh key secondary endpoint for reduction in fibroid volume was not achieved in either study.

Data showed changes in bone mineral density were comparable between the relugolix combination and placebo groups at the end of treatment in LIBERTY 1 and LIBERTY 2. The overall incidence of adverse events in the relugolix combination and placebo groups were also comparable (62% vs. 66% and 60% vs. 59%, respectively), including hot flashes (11% vs. 8% and 6% vs. 4%, respectively). There were no pregnancies reported in the

relugolix combination groups in either study.

Data from LIBERTY 1 and LIBERTY 2, in addition to the 28-week long-term extension study, were included in the New Drug Application for relugolix combination tablet for uterine fibroids, with an FDA decision expected by the June 1, 2021 target action date. Myovant previously announced results from the LIBERTY long-term extension study in February 2020. At one year, 87.7% of women receiving relugolix combination therapy met the responder criteria. In addition, women experienced, on average, an 89.9% reduction in menstrual blood loss from baseline at one year. Changes in bone mineral density and the incidence of adverse events were consistent with those in LIBERTY 1 and LIBERTY 2.

About Uterine Fibroids
Uterine fibroids are noncancerous tumors that develop in or on the muscular walls of the uterus and are among the most common reproductive tract tumors in women. In addition to an individual's genetic predisposition, estrogens are well known to play an important role in the regulation of fibroid growth.

Although uterine fibroids are benign tumors, they can cause debilitating symptoms such as heavy menstrual bleeding (frequently resulting in anemia and fatigue), pain (including painful periods, abdominal pain, painful intercourse, backache), increased abdominal girth and bloating, urinary frequency or retention, constipation, pregnancy loss, and, in some cases, infertility. These symptoms can also lead to loss of productivity at work, limitations in normal activities of daily living, and social embarrassment.

An estimated five million women in the U.S. suffer from symptoms of uterine fibroids, and an estimated three million women are inadequately treated by current medical therapy and require further treatment.

About Myovant Sciences
Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. We have one FDA-approved medicine, ORGOVYXTM (relugolix), for adult patients with advanced prostate cancer. Our lead product candidate, relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5mg), 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 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; quotes regarding the potential for relugolix combination tablet for uterine fibroids; the expected timing and strength of Myovant's regulatory filings; and Myovant's vision for a one pill, once-a-day, treatment option suitable for long-term use in uterine fibroids.

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, the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities and whether regulatory authorities will be

satisfied with the design of and results from the clinical studies. 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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