Myovant Sciences Announces Corporate Updates and Financial Results for Second Quarter Fiscal Year 2020

November 12, 2020

- *FDA Priority Review of New Drug Application (NDA) for relugolix monotherapy tablet for advanced prostate cancer on track for decision by December 20, 2020 target action date*
- *NDA for relugolix combination tablet for uterine fibroids accepted for FDA review with a decision expected by June 1, 2021 target action date*
- *Positive one-year efficacy and safety data from Phase 3 LIBERTY program for relugolix combination therapy in women with uterine fibroids, including bone mineral density data, presented at the American Society for Reproductive Medicine (ASRM) 2020 Virtual Congress*
- *Positive efficacy and safety data from Phase 3 SPIRIT program for relugolix combination therapy in women with endometriosis-associated pain presented at the ASRM 2020 Virtual Congress*

BASEL, Switzerland, Nov. 12, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced corporate updates and financial results for the second quarter fiscal year 2020.

“I am very pleased with the significant progress we made during the second fiscal quarter in advancing both relugolix monotherapy tablet and relugolix combination tablet toward potential regulatory approvals, while preparing for commercialization in advanced prostate cancer, uterine fibroids, and endometriosis,” said Lynn Seely, M.D., chief executive officer of Myovant Sciences, Inc. “We have assembled a strong and highly-experienced team, spanning medical affairs, market access, commercial operations, marketing, and sales, which will enable us to rapidly and efficiently deliver relugolix monotherapy tablet to urologists, medical oncologists, and their patients, if approved, for our first commercial launch.”

Second Quarter Fiscal Year 2020 and Recent Corporate Updates

Relugolix Clinical Programs

- **Prostate Cancer:**
    - Relugolix monotherapy tablet is under Priority Review by the U.S. Food and Drug Administration (FDA) and is on track for a decision by its December 20, 2020 target action date. The NDA is supported by the positive Phase 3 HERO study results, including a 97% responder rate and six positive key secondary endpoints. Relugolix also demonstrated a lower incidence of major adverse cardiovascular events compared to leuprolide acetate, the current standard of care. The Phase 3 HERO study results were published in the *New England Journal of Medicine* on June 4, 2020.
    - On September 29, 2020, Myovant announced results of an additional secondary endpoint of castration resistance-free survival assessed in the subgroup of men with metastatic prostate cancer from the Phase 3 HERO study of relugolix monotherapy in advanced prostate cancer. Relugolix monotherapy had a similar rate of castration resistance-free survival compared to leuprolide acetate (74% vs. 75%, respectively), and did not achieve statistical superiority ($p = 0.84$).
    - On October 19, 2020, Myovant presented an economic analysis of the Phase 3 HERO data at the Academy of Managed Care Pharmacy (AMCP) Nexus 2020 Virtual Meeting, demonstrating that treatment with oral relugolix may prevent one major adverse cardiovascular event for every 31 patients treated versus patients receiving leuprolide injections.
- **Uterine Fibroids:**
    - In August 2020, the FDA accepted Myovant’s NDA for once-daily, oral relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids, setting a target action date of June 1, 2021.
    - On September 14, 2020, Myovant announced one-year data on bone mineral density (BMD) from the Phase 3 LIBERTY program. The BMD results from the LIBERTY program demonstrated maintenance of BMD through one year and were consistent with those observed in a separate prospective observational study of untreated, age-matched women with uterine fibroids. These findings were presented at the American Society for Bone and

Mineral Research (ASBMR) 2020 Annual Meeting Virtual Event, held on September 11-15, 2020.

- On October 21, 2020, Myovant announced the presentation of data at the American Society for Reproductive Medicine (ASRM) 2020 Virtual Congress, including long-term extension data in women with symptomatic uterine fibroids. Results indicated that women experienced, on average, a 90% reduction in menstrual blood loss from baseline at one year. Additionally, 87.7% of women achieved the responder criteria for reduction in menstrual blood loss at one year, and lumbar spine and total hip BMD were maintained over one year. A poster presentation also described a validated exposure-response model simulating long-term effects of relugolix combination therapy on BMD at the lumbar spine that projected maintenance of BMD for at least three years. Other data from the LIBERTY program – including improvement in quality of life, reduction in menstrual blood loss in the first treatment cycle, and reduction in uterine fibroid-associated pain – were also presented.

- Additional data from the Phase 1 ovulation inhibition study from 67 healthy women treated with relugolix combination therapy, resulting in 100% ovulation inhibition and 100% return to ovulation or menses after discontinuation of treatment, were also presented at the ASRM 2020 Virtual Congress.

- **Endometriosis**:

  - Data from the replicate Phase 3 SPIRIT 1 and SPIRIT 2 studies were presented at the ASRM 2020 Virtual Congress on October 20, 2020 in an oral presentation named the Prize Paper by the Endometriosis Special Interest Group. Relugolix combination therapy resulted in clinically meaningful reductions in dysmenorrhea and non-menstrual pelvic pain, compared with placebo over 24 weeks of therapy ($p < 0.0001$) in each study. Changes in BMD over 24 weeks were minimal in the relugolix combination therapy groups.

COVID-19 Pandemic Environment

- Myovant's priorities during the COVID-19 pandemic are protecting the health and safety of its employees and patients while continuing its mission to redefine care for women and for men. To date, the impact of the COVID-19 pandemic on Myovant's ability to advance its clinical studies, regulatory activities, and preparation for the potential commercialization of its product candidates has been limited, and all of Myovant's publicly announced milestones remain on track. However, if the COVID-19 pandemic persists, and depending on the further evolution of the pandemic and its effects on Myovant's activities, Myovant may experience more significant impacts on its business operations.

Expected Upcoming Milestones

- Relugolix monotherapy tablet for advanced prostate cancer FDA target action date of December 20, 2020.

- Data from the LIBERTY randomized withdrawal study expected in the first quarter of calendar year 2021.

- One-year efficacy and safety data from the SPIRIT extension study expected in the first quarter of calendar year 2021.

- Relugolix combination tablet for uterine fibroids FDA target action date of June 1, 2021.

- Marketing Authorization Application (MAA) submission to European Medicines Agency (EMA) for relugolix monotherapy tablet for advanced prostate cancer in the first half of calendar year 2021.

- NDA submission for relugolix combination tablet for the treatment of women with endometriosis-associated pain expected in the first half of calendar year 2021.

- European Commission decision on the uterine fibroids MAA expected in 2021. If approved, this launch will be executed by Gedeon Richter, Myovant's commercialization partner for relugolix combination tablet for the uterine fibroids and endometriosis indications in Europe and certain other international markets.

- MAA submission to EMA for relugolix combination tablet for the treatment of women with endometriosis-associated pain expected in 2021. Gedeon Richter will be the MAA sponsor.

Second Quarter Fiscal Year 2020 Financial Summary

Research and development (R&D) expenses in the three months ended September 30, 2020, were $40.5 million compared to $50.8 million for the comparable prior year period. The decrease in R&D expenses reflects a decrease in clinical study costs as a result of the completion and continued wind down of Myovant's Phase 3 LIBERTY, HERO, and SPIRIT studies. This decrease was partially offset primarily by increased expenses by the medical affairs organization in preparation for Myovant's anticipated commercial launches, if approved, of relugolix monotherapy tablet for men with

advanced prostate cancer and relugolix combination tablet for the women's health indications, as well as an increase in personnel expenses.

General and administrative (G&A) expenses in the three months ended September 30, 2020, were $31.3 million compared to $16.6 million for the comparable prior year period. The increase was primarily due to increases in expenses related to commercial readiness activities, personnel-related expenses, and other general overhead expenses to support Myovant's organizational growth and anticipated commercial launches, if approved, of relugolix monotherapy tablet for men with advanced prostate cancer and relugolix combination tablet for the women's health indications.

Interest expense was $2.1 million in the three months ended September 30, 2020, compared to $3.8 million in the comparable prior year period. The decrease in interest expense was driven by lower interest rates associated with the Sumitomo Dainippon Pharma Loan Agreement as compared to Myovant's previously outstanding debt obligations, which were repaid in December 2019.

Interest income in the three months ended September 30, 2020, was less than $0.1 million compared to $0.9 million for the comparable prior year period. The decrease was primarily due to decreases in interest rates and lower balances in cash equivalents and marketable securities.

Other (income) expense, net in the three months ended September 30, 2020, was income of $6.7 million compared to expenses of $0.1 million for the comparable prior year period. This was primarily the result of a foreign currency exchange gain on Myovant's outstanding balance under the Sumitomo Dainippon Pharma Loan Agreement during the three months ended September 30, 2020 for which there was no such gain in the comparable prior year period.

Net loss for the three months ended September 30, 2020, was $67.1 million compared to $70.6 million for the comparable prior year period. On a per common share basis, net loss was $0.75 and $0.79 for the three months ended September 30, 2020, and 2019, respectively.

Capital resources: Cash, cash equivalents, marketable securities, and committed amounts available under the Sumitomo Dainippon Pharma Loan Agreement totaled $257.6 million as of September 30, 2020, and consisted of $111.3 million of cash, cash equivalents, and marketable securities and $146.3 million of available borrowing capacity under the Sumitomo Dainippon Pharma Loan Agreement.

On August 5, 2020, Myovant obtained a debt commitment letter (amended on September 29, 2020) from Sumitomo Dainippon Pharma, pursuant to which, subject to the terms and conditions set forth therein, Sumitomo Dainippon Pharma has committed to provide Myovant with an additional $200.0 million, low-interest, five-year term loan, which, subject to negotiation of a definitive agreement, will bring its total financing support for Myovant to $600.0 million. Including the additional debt commitment, cash and committed funding as of September 30, 2020 totaled approximately $460.0 million.

Conference Call
As previously announced, Myovant will hold a webcast and conference call at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) today, November 12, 2020, to discuss corporate updates and financial results for its second fiscal quarter 2020, ended September 30, 2020. 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. Institutional 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.

The webcast will be archived on Myovant's Investor Relations website following the call.

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 monotherapy tablet (120 mg) is under regulatory review in the U.S. for men 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 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 monotherapy tablet (120 mg) is under regulatory review in the U.S. for men 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 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 merger in 2005 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.

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 and Urovant, and wholly owns Enzyvant, Spirovant and Altavant. 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.

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 reflecting Myovant Sciences' expectations, including those statements under the caption "Expected Upcoming Milestones"; statements and quotes regarding Myovant Sciences' aspiration to redefine care for women and for men; statements and quotes regarding Myovant's belief that it has assembled a strong and highly-experienced team, spanning medical affairs, market access, commercial operations, marketing and sales, which will enable it to rapidly and efficiently deliver relugolix monotherapy tablet to urologists, medical oncologists, and their patients, if approved; the commitments of Sumitomo Dainippon Pharma to Myovant, including statements regarding the expected terms of a $200 million debt facility; and the expected timing of results from Myovant Sciences' ongoing clinical trials.

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 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 to be 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.

MYOVANT SCIENCES LTD.
Condensed Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share data)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
License and milestone revenue	$ —	$ —	$ 33,333	$ —
Operating expenses:				
Research and development [1]	40,521	50,803	84,707	101,920
General and administrative [1]	31,316	16,603	54,144	30,755
Total operating expenses	71,837	67,406	138,851	132,675
Loss from operations	(71,837)	(67,406)	(105,518)	(132,675)
Interest expense	—	3,788	—	7,581
Interest expense (related party)	2,115	—	4,299	—
Interest income	(38)	(942)	(146)	(1,708)
Other (income) expense, net	(6,718)	121	(10,287)	(584)
Loss before income taxes	(67,196)	(70,373)	(99,384)	(137,964)
Income tax (benefit) expense	(134)	195	538	508
Net loss	$ (67,062)	$ (70,568)	$ (99,922)	$ (138,472)
Net loss per common share — basic and diluted	$ (0.75)	$ (0.79)	$ (1.12)	$ (1.68)
Weighted average common shares outstanding — basic and diluted	89,744,142	88,798,398	89,523,389	82,667,061

[1] Includes the following share-based compensation expenses:

Research and development	$ 3,725	$ 3,618	$ 7,749	$ 6,166
General and administrative	$ 3,199	$ 4,313	$ 6,987	$ 8,217

MYOVANT SCIENCES LTD.
Condensed Consolidated Balance Sheets
(Unaudited, in thousands)

	September 30, 2020	**March 31, 2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 94,210	$ 76,644
Marketable securities	17,086	2,997
Prepaid expenses and other current assets	5,612	8,269
Total current assets	116,908	87,910
Property and equipment, net	2,808	2,497
Operating lease right-of-use asset	10,423	11,146
Other assets	5,634	4,373
Total assets	$ 135,773	$ 105,926
Liabilities and Shareholders' Deficit		
Current liabilities:		

Accounts payable	$ 7,008	$ 15,334
Interest payable (related party)	—	15
Accrued expenses	40,141	29,060
Deferred revenue	16,667	40,000
Operating lease liability	1,657	1,516
Amounts due to related parties	1,284	—
Total current liabilities	66,757	85,925
Long-term operating lease liability	10,127	10,996
Long-term debt, less current maturities (related party)	253,700	113,700
Other	4,968	3,582
Total liabilities	335,552	214,203
Total shareholders' deficit	(199,779)	(108,277)
Total liabilities and shareholders' deficit	$ 135,773	$ 105,926

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