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

August 11, 2020

- *New Drug Application (NDA) for relugolix monotherapy tablet in advanced prostate cancer accepted for Priority Review by the FDA with target action date of December 20, 2020*
- *NDA for relugolix combination tablet in uterine fibroids submitted in May 2020*
- *Additional USD 200 million low-interest, five-year term loan commitment from Sumitomo Dainippon Pharma and commercial collaboration agreement with Sunovion Pharmaceuticals increases financial flexibility and provides access to well-established commercial infrastructure*
- *Co-primary endpoints and seven key secondary endpoints achieved in second Phase 3 study in women with endometriosis*
- *Phase 3 data in advanced prostate cancer presented in oral presentation at the American Society of Clinical Oncology (ASCO)'s ASCO20 Virtual Scientific Program with simultaneous publication in the New England Journal of Medicine*

BASEL, Switzerland, Aug. 11, 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 first quarter fiscal year 2020.

"I am very proud of the many recent accomplishments achieved by Myovant, including positive results from our second Phase 3 study in women with endometriosis, publication of our advanced prostate cancer data in the *New England Journal of Medicine*, and progress in our commercial readiness, particularly now that relugolix is under Priority Review by the FDA for advanced prostate cancer and the NDA for relugolix combination therapy for uterine fibroids has been submitted for review," said Lynn Seely, M.D., chief executive officer of Myovant Sciences. "The additional financial commitment from Sumitomo Dainippon Pharma and our commercial collaboration agreement with Sunovion we expect will further advance our vision to potentially provide one pill, once-a-day treatment options to the women and men with these common diseases."

First Quarter Fiscal Year 2020 and Recent Corporate Updates

Relugolix Phase 3 Clinical Programs

- **Prostate cancer:** In June 2020, the U.S. Food and Drug Administration (FDA) accepted for Priority Review Myovant's New Drug Application (NDA) for once-daily, oral relugolix (120 mg) for the treatment of men with advanced prostate cancer, setting a target action date of December 20, 2020. In May 2020, efficacy and safety data from the Phase 3 HERO study of relugolix in men with advanced prostate cancer were simultaneously published in the *New England Journal of Medicine* and presented at the American Society of Clinical Oncology (ASCO)'s ASCO20 Virtual Scientific Program. In July 2020, these data were also presented in an oral presentation during the American Urological Association (AUA)'s 2020 Virtual Experience.

- **Uterine fibroids:** In May 2020, Myovant submitted an NDA for once-daily, oral relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for the treatment of women with heavy menstrual bleeding associated with uterine fibroids. In July 2020, Myovant presented additional data from the Phase 3 LIBERTY program showing improvement in patient-reported outcomes and in hemoglobin levels in women with anemia, as well as detailed data from a separate ovulation inhibition study, at the European Society of Human Reproduction and Embryology (ESHRE)'s virtual 36th Annual Meeting.

- **Endometriosis**: In April 2020, Myovant announced that the SPIRIT 2 Phase 3 study evaluating the efficacy and safety of once-daily, oral relugolix combination therapy in women with pain associated with endometriosis met the co-primary efficacy endpoints with 75.2% and 66.0% of women achieving clinically-meaningful reductions in dysmenorrhea and non-menstrual pelvic pain, respectively. In June 2020, Myovant announced that the replicate SPIRIT 1 Phase 3 study also met the co-primary efficacy endpoints with 74.5% and 58.5% of women achieving clinically-meaningful reductions in dysmenorrhea and non-menstrual pelvic pain, respectively. Relugolix was generally well-tolerated and resulted in minimal bone mineral density loss over 24 weeks in both studies.

Corporate

- On August 5, 2020, Myovant announced an additional USD 200 million low-interest, five-year term loan commitment from Sumitomo Dainippon Pharma, which, subject to the negotiation of a definitive agreement, will bring its total financing support for Myovant to USD 600 million, further bolstering Myovant's cash and committed funding, and increasing Myovant's financing flexibility as it prepares for multiple potential product launches.

- On August 5, 2020, Myovant also announced that it entered into a three-year commercial collaboration agreement with Sunovion Pharmaceuticals Inc. (Sunovion). Under the agreement, Sunovion will provide third-party logistics, trade and retail distribution, contract operations, and market access account management services to Myovant and will become a non-exclusive distributor of relugolix for prostate cancer and the exclusive distributor of relugolix combination tablet for uterine fibroids and endometriosis in the U.S.

- In June 2020, Myovant partnered with BlackDoctor.org, Evidation Health, and Movember to launch Forward Momentum, a cross-sector coalition working on innovative projects to increase diversity in research and develop new digital resources for men with prostate cancer.

COVID-19 Pandemic Environment

- Myovant's priorities during the COVID-19 pandemic are protecting the health and safety of its employees 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

- Castration-resistance free survival data for prostate cancer expected in the third quarter of calendar year 2020.

- Data from the uterine fibroids cohort in the prospective observational bone mineral density study expected in the third quarter of calendar year 2020.

- Relugolix monotherapy tablet for advanced prostate cancer 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.

First Quarter Fiscal Year 2020 Financial Summary

License and milestone revenue in the three months ended June 30, 2020, was $33.3 million and represents the partial recognition of revenue associated with the $40 million upfront payment and a $10 million regulatory milestone payment under the Development and Commercialization Agreement Myovant entered into with Gedeon Richter (Richter) in March 2020. Myovant recognizes revenue as it satisfies its performance obligation to Richter. There were no such amounts in the comparable prior year period.

Research and development (R&D) expenses in the three months ended June 30, 2020, were $44.2 million compared to $51.1 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 wind down of Myovant's Phase 3 LIBERTY, HERO, and SPIRIT studies. This decrease was partially offset by an increase in other R&D expenses related predominantly to regulatory activities in connection with regulatory submissions for relugolix combination tablet and relugolix monotherapy tablet, including NDA submission fees of $5.8 million, expenses associated with the build out of Myovant's medical affairs organization in connection with preparations for Myovant's anticipated commercial launches, as well as increases in personnel-related expenses.

General and administrative (G&A) expenses in the three months ended June 30, 2020, were $22.8 million compared to $14.2 million for the comparable prior year period. The increase was primarily due to increases in expenses related to commercial operations activities in advance of potential future regulatory approvals of relugolix combination tablet and relugolix monotherapy tablet, personnel-related expenses, and other general overhead, administrative, and information technology expenses to support Myovant's organizational growth.

Interest expense was $2.2 million in the three months ended June 30, 2020, related to the Sumitomo Dainippon Pharma Loan Agreement compared to $3.8 million in the comparable prior year period, related to Myovant's previously outstanding financing arrangements with NovaQuest and Hercules. The decrease in interest expense was driven by a lower interest rate associated with the Sumitomo Dainippon Pharma Loan Agreement as compared to the previously outstanding obligations to NovaQuest and Hercules, which were repaid in December 2019. Myovant expects its interest expense to increase in future periods as a result of further anticipated draws under the Sumitomo Dainippon Pharma Loan Agreement.

Interest income in the three months ended June 30, 2020, was $0.1 million compared to $0.8 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, net in the three months ended June 30, 2020, was $3.6 million compared to $0.7 million for the comparable prior year period. This increase was primarily the result of a foreign currency exchange gain on Myovant's outstanding balance under the Sumitomo Dainippon Pharma Loan Agreement.

Net loss for the quarter ended June 30, 2020, was $32.9 million compared to $67.9 million for the comparable prior year period. The decrease in the net loss for the quarter was driven primarily by the recognition of $33.3 million of license and milestone revenue from the Gedeon Richter Development and Commercialization Agreement. On a per common share basis, net loss was $0.37 and $0.89 for the quarters ended June 30, 2020, and 2019, respectively.

Capital resources: Cash, cash equivalents, marketable securities, and committed funding from Sumitomo Dainippon Pharma totaled $306.0 million as of June 30, 2020, and consisted of $99.7 million of cash, cash equivalents, and marketable securities and $206.3 million of available borrowing capacity under the Sumitomo Dainippon Pharma Loan Agreement. Additional funds may be drawn down by Myovant once per calendar quarter, subject to certain terms and conditions, including consent of Myovant's Board of Directors. In July 2020, Myovant borrowed an additional $60.0 million under the Sumitomo Dainippon Pharma Loan Agreement. On August 5, 2020, Myovant announced a USD 200 million, low-interest, five-year term loan commitment from Sumitomo Dainippon Pharma, which, subject to negotiation of a definitive agreement, will bring its total financing support for Myovant to USD 600 million.

About Relugolix
Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces ovarian estradiol, a hormone known to stimulate the growth of uterine fibroids and endometriosis, and testicular testosterone, a hormone known to stimulate the growth of prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under development for women with uterine fibroids and for women with endometriosis. Relugolix monotherapy tablet (120 mg once daily) is under regulatory review in the U.S. for men with advanced prostate cancer.

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 combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under development for women with uterine fibroids and for women with endometriosis. Relugolix monotherapy tablet (120 mg once daily) is under regulatory review in the U.S. for men with advanced prostate cancer. 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. Forward-looking statements include all statements regarding Myovant Sciences' intent, belief, or expectations regarding future events or results and can be identified by words such as "anticipate," "aspire," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words or other similar expressions or variations, although not all forward-looking statements contain these identifying words. In this press release, forward-looking statements include, but are not limited to, statements and quotes regarding Myovant Sciences' aspiration to redefine care for women and for men; the statement regarding the benefits of the additional financial commitment from Sumitomo Dainippon Pharma and the commercial collaboration agreement with Sunovion, including advancement of Myovant Sciences' vision to potentially provide one pill, once-a-day treatment options to the women and men with these common diseases; the USD 200 million loan commitment from Sumitomo Dainippon Pharma; the characterizations of data from Myovant Sciences' clinical trials; the timing of results from Myovant Sciences' ongoing clinical trials; the timing and anticipated actions on Myovant Sciences' regulatory filings; expected milestones; and the potential business interruptions due to the COVID-19 pandemic environment. 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 August 11, 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. In addition, the loan commitment letter from Sumitomo Dainippon Pharma for an additional USD 200 million low-interest, five-year term loan is subject to the terms and conditions, including the negotiation of the definitive agreement for such loan, and there is no guarantee that Myovant Sciences will be able to satisfy all conditions or that the parties will be able to negotiate the definitive agreement which, if that does not occur, would result in Myovant Sciences not obtaining the loan. 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 June 30,	
	2020	**2019**
License and milestone revenue	$ 33,333	$ —

Operating expenses:		
Research and development [1]	44,186	51,117
General and administrative [1]	22,828	14,152
Total operating expenses	67,014	65,269
Loss from operations	(33,681)	(65,269)
Interest expense	—	3,793
Interest expense (related party)	2,184	—
Interest income	(108)	(766)
Other income, net	(3,569)	(705)
Loss before income taxes	(32,188)	(67,591)
Income tax expense	672	313
Net loss	$ (32,860)	$ (67,904)
Net loss per common share — basic and diluted	$ (0.37)	$ (0.89)
Weighted average common shares outstanding — basic and diluted	89,300,210	76,468,347

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

Research and development	$ 4,024	$ 2,548
General and administrative	$ 3,788	$ 3,904

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

	June 30, 2020	**March 31, 2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 84,726	$ 76,644
Marketable securities	14,970	2,997
Prepaid expenses and other current assets	9,370	8,269
Total current assets	109,066	87,910
Property and equipment, net	2,453	2,497
Operating lease right-of-use asset	10,790	11,146
Other assets	4,373	4,373
Total assets	$ 126,682	$ 105,926
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 5,388	$ 15,334
Interest payable (related party)	24	15
Accrued expenses	28,920	29,060
Deferred revenue	16,667	40,000
Operating lease liability	1,585	1,516
Total current liabilities	52,584	85,925
Long-term operating lease liability	10,571	10,996
Long-term debt, less current maturities (related party)	193,700	113,700
Other	4,437	3,582
Total liabilities	261,292	214,203
Total shareholders' deficit	(134,610)	(108,277)
Total liabilities and shareholders' deficit	$ 126,682	$ 105,926

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