Myovant Sciences Provides Recent Corporate Updates and Reports Financial Results for Fourth Fiscal Quarter and Full Fiscal Year Ended March 31, 2020

May 18, 2020

- Co-primary endpoints and six key secondary endpoints met in Phase 3 SPIRIT 2 study in women with endometriosis, with results from the Phase 3 SPIRIT 1 study expected in the second quarter of calendar year 2020

- New Drug Application (NDA) submitted for relugolix monotherapy tablet for men with advanced prostate cancer, with castration resistance-free survival results expected in the third quarter of calendar year 2020

- Marketing Authorization Application for relugolix combination tablet for women with uterine fibroids submitted and currently under evaluation by the European Medicines Agency, with NDA submission expected in May 2020

- Strategic partnership with Gedeon Richter formed to accelerate the potential launch of relugolix combination tablet for uterine fibroids and endometriosis in certain territories outside the U.S.

BASEL, Switzerland, May 18, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: **MYOV**), a healthcare company focused on redefining care for women and for men, today announced recent corporate updates and reported financial results for the fourth fiscal quarter and full fiscal year ended March 31, 2020.

"I am tremendously proud of the many accomplishments of the Myovant team over the last year, with four positive Phase 3 studies, multiple regulatory submissions, and a strategic partnership with Gedeon Richter to accelerate the potential commercialization of relugolix combination tablet," said Lynn Seely, M.D., chief executive officer of Myovant Sciences. "We look forward to submitting our NDA in uterine fibroids this month and sharing the SPIRIT 1 results later this quarter, as we continue to realize our vision of redefining care for the millions of women and men with uterine fibroids, endometriosis, and prostate cancer."

Fourth Fiscal Quarter 2019 and Recent Business Highlights

Relugolix Clinical Programs

- In March 2020, Myovant announced the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) 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 moderate to severe symptoms associated with uterine fibroids. The MAA submission has completed validation and is now under evaluation by the EMA. The MAA submission was supported by efficacy and safety data from the Phase 3 LIBERTY program which consisted of two multinational, replicate pivotal clinical studies, LIBERTY 1 and 2, as well as data from a long-term extension study of relugolix combination therapy. Myovant expects to submit an NDA for relugolix combination tablet in uterine fibroids in May 2020.
- In April 2020, Myovant announced that the Phase 3 SPIRIT 2 study evaluating the safety and efficacy of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) over 24 weeks in 623 women with endometriosis met its co-primary efficacy endpoints with a 75.2% response rate for dysmenorrhea (menstrual pain) and a 66.0% response rate for non-menstrual pelvic pain, while achieving six key secondary endpoints and demonstrating minimal bone mineral density loss. Myovant expects to report top-line results from a replicate Phase 3 study, SPIRIT 1, in the second quarter of calendar year 2020.
- In April 2020, Myovant also announced that in an ovulation inhibition study relugolix combination therapy achieved 100% ovulation inhibition in 67 healthy women with no women ovulating during the 84-day treatment period, as evaluated by the Hoogland-Skouby assessment scale (score < 5). Furthermore, 100% of women resumed ovulation or menses upon discontinuation of treatment with an average time to ovulation of 23.5 days.
- In April 2020, Myovant announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for once-daily, oral relugolix monotherapy tablet (120 mg) for the treatment of men with advanced prostate cancer. The NDA submission was supported by efficacy and safety data from the Phase 3 HERO study, a randomized pivotal study comparing relugolix monotherapy tablet versus leuprolide acetate. Myovant will present new efficacy and cardiovascular safety data from the HERO study in an oral presentation at the American Society of Clinical Oncology (ASCO)'s ASCO20 Virtual Scientific Program on May 29, 2020. Myovant expects to report additional data from the HERO study measuring castration resistance-free survival in approximately 430 men in the third quarter of calendar year 2020.

Corporate

- In March 2020, Myovant and Gedeon Richter Plc. (Richter), a major pharmaceutical company in Central Eastern Europe focused on women's health, entered into an exclusive license agreement for Richter to commercialize relugolix

combination tablet for uterine fibroids and endometriosis in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand. Under the agreement, Myovant received an upfront payment of $40 million and is eligible to receive up to $40 million in regulatory milestones (of which $10 million was received in April 2020) and $107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval. Myovant retains all rights to relugolix combination tablet in the U.S. and Canada, as well as rights to relugolix in other therapeutic areas outside of women's health.

COVID-19 Pandemic Environment

- 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.

Fourth Fiscal Quarter and Full Fiscal Year 2019 Financial Summary

Research and development (R&D) expenses for the quarter ended March 31, 2020, were $41.7 million compared to $59.0 million for the comparable prior year period. R&D expenses for the fiscal year ended March 31, 2020, were $192.6 million, compared to $222.6 million for the prior fiscal year. R&D expenses for the periods presented primarily include expenses related to Myovant's Phase 3 clinical programs, manufacturing expenses, as well as personnel-related expenses for employees engaged in R&D activities. R&D expenses related to Myovant's clinical programs have continued to decline, driven primarily by the wind down of Myovant's Phase 3 studies. The decrease in relugolix Phase 3 study costs were partially offset by increases in other R&D expenses related predominantly to regulatory activities in connection with regulatory submissions for relugolix combination tablet and relugolix monotherapy tablet in multiple indications and jurisdictions and 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 expenses, share-based compensation, and other R&D expenses. For the year ended March 31, 2020, R&D expenses include $1.8 million of share-based compensation related to the accelerated vesting of certain equity awards as a result of a change in control in Myovant in connection with the closing of a transaction between Roivant and Sumitomo Dainippon Pharma.

General and administrative (G&A) expenses for the quarter ended March 31, 2020, were $22.4 million compared to $12.5 million for the comparable prior year period. G&A expenses for the fiscal year ended March 31, 2020, were $82.3 million, compared to $42.2 million for the prior fiscal year. The increase in G&A expenses for the quarter and the fiscal year ended March 31, 2020 were 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 share-based compensation expenses, as well as professional services fees, and other general overhead, administrative and information technology expenses to support Myovant's headcount growth and expanding operations. For the year ended March 31, 2020, G&A expenses include certain one-off increases as a result of the change in control in Myovant, namely $10.2 million in share-based compensation expense related to the accelerated vesting of certain equity awards as well as a $3.6 million capital tax accrual.

Interest expense for the quarters ended March 31, 2020 and 2019, was $0 and $3.9 million, respectively. On December 31, 2019, Myovant repaid all of its outstanding debt obligations to NovaQuest and Hercules and as a result there was no interest expense during the quarter ended March 31, 2020. For the year ended March 31, 2020, interest expense was $11.2 million, compared to $8.8 million for the comparable prior year period, reflecting higher outstanding debt balances with NovaQuest and Hercules until the debt repayment on December 31, 2019.

Loss on extinguishment of debt for the year ended March 31, 2020, was $4.9 million, which resulted from the early retirement of Myovant's outstanding obligations to NovaQuest and Hercules. There were no such amounts in the other periods presented.

Interest expense (related party) for the quarter and year ended March 31, 2020, was $1.4 million in relation to Myovant's outstanding debt of $113.7 million to Sumitomo Dainippon Pharma, which did not exist in the year ended March 31, 2019.

Interest income for the quarter and year ended March 31, 2020, was $0.2 million and $2.6 million, respectively. There was interest income of $0.8 million and $0.9 million for the quarter and year ended March 31, 2019, respectively.

Net loss for the quarter ended March 31, 2020, was $64.9 million, compared to $75.0 million for the comparable prior year period. Net loss for the fiscal year ended March 31, 2020, was $289.0 million, compared to $273.6 million for the prior fiscal year. On a per common share basis, net loss was $0.73 and $1.07 for the quarters ended March 31, 2020 and 2019, respectively, and $3.37 and $4.09 for the years ended March 31, 2020 and 2019, respectively.

Capital resources: Cash, cash equivalents, marketable securities, and committed funding totaled $365.9 million as of March 31, 2020, and consisted of $79.6 million of cash, cash equivalents, and marketable securities and $286.3 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 April 2020, Myovant borrowed an additional $80.0 million under the Sumitomo Dainippon Pharma Loan Agreement. In April 2020, Myovant received a $10.0 million regulatory milestone payment from Richter.

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

About MVT-602
MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Kisspeptin, the ligand, is a naturally-occurring peptide that stimulates GnRH release and is

required for puberty and maintenance of normal reproductive function, including production of sperm, follicular maturation and ovulation, and production of estrogen and progesterone in women and testosterone in men. A Phase 2a clinical study in healthy female volunteers to characterize the dose-response curve in a minimal controlled ovarian stimulation setting has been completed.

About Myovant Sciences
Myovant Sciences aspires to be the leading healthcare company focused on redefining care for women and for men. The company's lead product candidate is relugolix, a once-daily, oral GnRH receptor antagonist. The company has three late-stage clinical programs for relugolix in uterine fibroids, endometriosis, and prostate cancer. The company is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, that has completed a Phase 2a study for the treatment of female infertility as part of assisted reproduction. Takeda Pharmaceuticals International AG, a subsidiary of Takeda Pharmaceutical Company Limited, the originator of relugolix, granted the company a worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive license to develop and commercialize MVT-602 in all countries worldwide. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is the majority shareholder of Myovant. For more information, please visit the company's 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 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.

About Sumitomo Dainippon Pharma
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.

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; expectations to submit an NDA for relugolix combination tablet in uterine fibroids in May 2020; report top-line results from SPIRIT 1, a Phase 3 study of relugolix combination therapy for the treatment of women with endometriosis, in the second quarter of calendar year 2020; present new efficacy and cardiovascular safety data from the HERO study at the ASCO20 Virtual Scientific Program; and report castration resistance-free survival results of relugolix for the treatment of men with advanced prostate cancer in the third quarter of calendar year 2020, as well as 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 filed on February 10, 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 March 31,		Years Ended March 31,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development [1]	$ 41,713	$ 59,019	$ 192,560	$ 222,607
General and administrative [1]	22,430	12,481	82,327	42,219
Total operating expenses	64,143	71,500	274,887	264,826
Interest expense	—	3,913	11,222	8,821
Loss on extinguishment of debt	—	—	4,851	—
Interest expense (related party)	1,425	—	1,441	—
Interest income	(247)	(804)	(2,552)	(881)
Other (income) expense, net	(470)	162	(1,621)	309
Loss before income taxes	(64,851)	(74,771)	(288,228)	(273,075)

Income tax expense	62	243	761	476
Net loss	$ (64,913)	$ (75,014)	$ (288,989)	$ (273,551)
Net loss per common share — basic and diluted	$ (0.73)	$ (1.07)	$ (3.37)	$ (4.09)
Weighted average common shares outstanding — basic and diluted	89,130,806	70,076,475	85,839,303	66,910,060

(1) Includes the following share-based compensation expenses:

Research and development (2)	$ 2,959	$ 1,914	$ 14,524	$ 7,161
General and administrative (3)	$ 3,114	$ 3,019	$ 25,727	$ 11,535

(2) For the year ended March 31, 2020, includes approximately $1.8 million related to the accelerated vesting of certain equity awards as a result of a change in control of Myovant.

(3) For the year ended March 31, 2020, includes approximately $10.2 million related to the accelerated vesting of certain equity awards as a result of a change in control of Myovant.

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

	March 31, 2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 76,644	$ 156,074
Marketable securities	2,997	—
Prepaid expenses and other current assets	8,269	10,194
Income tax receivable	—	524
Total current assets	87,910	166,792
Property and equipment, net	2,497	2,071
Operating lease right-of-use asset	11,146	—
Other assets	4,373	4,114
Total assets	$ 105,926	$ 172,977
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 15,334	$ 11,019
Interest payable	—	1,077
Interest payable (related party)	15	—
Accrued expenses	29,060	53,735
Deferred revenue	40,000	—
Operating lease liability	1,516	—
Current maturities of long-term debt	—	6,142
Total current liabilities	85,925	71,973
Deferred rent	—	1,157
Deferred interest payable	—	2,273
Long-term operating lease liability	10,996	—
Long-term debt, less current maturities	—	93,240
Long-term debt, less current maturities (related party)	113,700	—
Other	3,582	—
Total liabilities	214,203	168,643
Total shareholders' (deficit) equity	(108,277)	4,334
Total liabilities and shareholders' (deficit) equity	$ 105,926	$ 172,977

Investor Contact:
Frank Karbe
President and Chief Financial Officer
Myovant Sciences, Inc.
investors@myovant.com

SOURCE: Myovant Sciences

Source: Myovant Sciences, Inc.