Myovant Sciences Provides Recent Corporate Updates and Reports Financial Results for Second Fiscal Quarter Ended September 30, 2019

November 12, 2019

-Landmark Agreement with Sumitomo Dainippon Pharma to provide major financial backing and safeguards for minority shareholders

-Myovant to report top-line data from Phase 3 HERO study in advanced prostate cancer by the end of calendar year 2019 and Phase 3 SPIRIT studies in endometriosis in the first and second quarters of calendar year 2020

-Myovant secured commitment from Roivant Sciences and Sumitomo Dainippon Pharma for a priority review voucher (PRV) expected to become available in early December 2019

-Submission of New Drug Application (NDA) for uterine fibroids together with PRV now expected in April 2020 in order to include 12-month safety data to enhance prospects for labeled duration of use

BASEL, Switzerland, Nov. 12, 2019 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: **MYOV**), a healthcare company focused on developing innovative treatments for women's health and prostate cancer, today announced recent corporate updates and reported financial results for the second fiscal quarter ended September 30, 2019.

"Myovant continues to make great progress towards our milestones and is poised for a strong commercial launch of relugolix if approved, with two positive Phase 3 studies evaluating relugolix combination therapy in women with uterine fibroids and approximately $500 million in total cash and committed financing, including the Sumitomo Dainippon Pharma term loan facility," said Lynn Seely, M.D., President and CEO of Myovant Sciences. "Bringing a new treatment to the millions of women who suffer from uterine fibroids and endometriosis has been the key vision for the development of Myovant's relugolix combination tablet. The use of a priority review voucher enables us to expedite the review of our NDA while strengthening the data package in the submission to support this objective."

Second Fiscal Quarter 2019 and Recent Business Highlights

Relugolix Phase 3 Clinical Programs

- In July 2019, Myovant announced positive top-line data from LIBERTY 2, the second of two Phase 3 studies evaluating relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with uterine fibroids and heavy menstrual bleeding. Results from a separate bioequivalence study support submission to the FDA of a potential one tablet, once-daily dosing regimen of relugolix combination therapy. In addition, the 12-month safety data from the LIBERTY open-label extension study are expected in the first quarter of calendar year 2020.

- Roivant Sciences and Sumitomo Dainippon Pharma have committed to Myovant a priority review voucher (PRV) expected to become available in early December 2019. Myovant plans to use the PRV in conjunction with its NDA submission for a once-daily, relugolix combination tablet for the treatment of heavy menstrual bleeding and uterine fibroids, potentially decreasing the standard FDA review time. Myovant has decided to defer its NDA submission for a once-daily, relugolix combination tablet for the treatment of heavy menstrual bleeding and uterine fibroids until April 2020, which would allow inclusion of the complete 12-month safety data from the LIBERTY open-label extension study, key data that may positively impact the labeled duration of use of the combination tablet. The terms regarding how the PRV will be transferred to Myovant will be determined in connection with the closing of the Roivant-Sumitomo Dainippon Pharma transaction. The transfer is expected to be a related-party transaction and will not involve the issuance of Myovant shares. Myovant still plans to submit a Marketing Authorisation Application (MAA) to the European Medicines Agency in the first quarter of calendar year 2020.

- In July 2019, Myovant completed enrollment of an additional cohort of 139 men with metastatic prostate cancer in the Phase 3 HERO study in order to assess the secondary objective of demonstrating that relugolix can delay the time to progression of the lethal state of the disease, castration-resistant prostate cancer, as compared to leuprolide. Myovant expects the top-line data readout for the HERO study by the end of calendar year 2019, with results from this additional cohort, including the castration resistance-free survival endpoint, expected in the third quarter of calendar year 2020. Myovant also anticipates submitting its NDA for its once-daily, oral relugolix monotherapy tablet for men with advanced prostate cancer in the second quarter of calendar year 2020.

- In August and October 2019, Myovant completed patient recruitment for the Phase 3 SPIRIT 2 and SPIRIT 1 studies, respectively, evaluating the safety and efficacy of relugolix combination therapy in women with pain associated with endometriosis. Myovant expects to report top-line results from SPIRIT 2 and SPIRIT 1 in the first and second quarters of calendar year 2020, respectively.

Corporate

- In October 2019, Myovant entered into a landmark agreement with Sumitomo Dainippon Pharma to secure a $350 million low-interest, five-year term loan facility, with no payments due until the end of the term, and an Investors Rights Agreement, which is intended to provide safeguards to minority shareholders. The term loan facility and Investors Rights Agreement are expected to become effective in connection with the closing of Sumitomo Dainippon Pharma's transaction with Roivant.

Second Fiscal Quarter 2019 Financial Summary

Research and development (R&D) expenses for the quarter ended September 30, 2019, were $50.8 million compared to $53.8 million for the comparable prior year period. R&D expenses in both periods primarily include expenses related to Myovant's Phase 3 clinical studies, manufacturing expenses as well as personnel-related expenses for employees engaged in R&D activities. R&D expenses related to Myovant's clinical studies have continued to decline driven primarily by the wind down of Myovant's LIBERTY Phase 3 studies. The decrease in study costs were partially offset by increases in other R&D expenses related predominantly to Myovant's manufacturing activities in connection with preparations for Myovant's anticipated commercial launches and regulatory submissions for relugolix in multiple indications and jurisdictions, as well as increases in personnel expenses, share-based compensation expense, and other R&D expenses.

General and administrative (G&A) expenses for the quarter ended September 30, 2019, were $16.6 million compared to $10.3 million for the comparable prior year period. The increase primarily reflects increases in personnel-related expenses, share-based compensation, professional service fees, expenses related to commercial operations activities in advance of potential regulatory approvals of relugolix, and other general overhead and administrative expenses to support Myovant's headcount growth and expanding operations which was in part driven by the assumption of activities previously provided by Roivant.

Interest expense for the quarter ended September 30, 2019, was $3.8 million compared to $1.6 million in the comparable prior year period. The increase for the quarter was primarily the result of higher outstanding debt balances under Myovant's financing agreements as compared to the prior year period.

Interest income for the quarter ended September 30, 2019, was $0.9 million. There was no interest income for the quarter ended September 30, 2018. During the quarter ended September 30, 2019, a portion of Myovant's cash was invested in a combination of money market funds, commercial paper, and short-term corporate bonds. There were no such investments during the comparable prior year period.

Net loss for the quarter ended September 30, 2019, was $70.6 million, compared to $65.8 million for the comparable prior year period. The increase in the net loss for the quarter was driven primarily by the increase in costs outlined above. On a per common share basis, net loss was $0.79 and $0.99 for the quarters ended September 30, 2019, and 2018, respectively. The decrease in the net loss per common share for the quarter was due to an increase in the weighted-average common shares outstanding primarily as a result of Myovant's underwritten public equity offering in June 2019.

Capital resources: Cash, cash equivalents, and marketable securities totaled $157.6 million as of September 30, 2019. Myovant's term loan facility to be entered into with Sumitomo Dainippon Pharma, which is expected to become effective in connection with the close of the Sumitomo-Roivant transaction, is expected to provide an additional $350.0 million of capital to support Myovant's operations.

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 Sciences is developing a relugolix combination tablet (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) for women with heavy menstrual bleeding associated with uterine fibroids and for women with endometriosis-associated pain. Myovant is also evaluating relugolix monotherapy (120 mg once daily) in 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 innovative treatments for women's health and prostate cancer. 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, granted the company an exclusive, 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. For more information, please visit the company's website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn.

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 regarding Myovant Sciences' aspirations to become the leading healthcare company focused on innovative treatments for women's health and prostate cancer; the expected timing and terms of agreements with Sumitomo Dainippon Pharma, including an anticipated loan facility and Investors Rights Agreement; the expected timing of announcements of data from Myovant's clinical studies, including the Phase 3 HERO and SPIRIT studies; the expected timing of Myovant Sciences' uterine fibroids NDA submission to the FDA and Marketing Authorisation Application to

the European Medicines Agency; the potential for Myovant Sciences to obtain a priority review voucher from Roivant Sciences and Sumitomo Dainippon Pharma and the likelihood and timing of when such priority review voucher is expected to be available and transferred to Myovant Sciences.

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. 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 with the SEC on August 6, 2019, and in Myovant Sciences' future filings with the SEC including without limitation, Myovant Sciences' Quarterly Report on Form 10-Q expected to be filed with the SEC on or about November 12, 2019, as such risk factors may be amended, supplemented or superseded from time to time by other reports Myovant Sciences files with the SEC. In addition, the terms of the term loan facility, the Investors Rights Agreement and the priority review voucher transfer with Sumitomo Dainippon Pharma, although agreed to be entered into, have not yet been fully negotiated, and are expected to be negotiated, entered into and become effective in connection with the closing of Sumitomo Dainippon Pharma's transaction with Roivant Sciences. As a result, unexpected disagreements may arise in the negotiations of these agreements that may delay or prevent the entering into of these agreements; further, these agreements will only become effective upon closing of Sumitomo Dainippon Pharma's transaction with Roivant Sciences, which if the closing does not occur will cause these agreements not to become effective. 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, except as may be required by law.

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,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development [1]	$ 50,803	$ 53,813	$ 101,920	$ 105,154
General and administrative [1]	16,603	10,310	30,755	19,052
Total operating expenses	67,406	64,123	132,675	124,206
Interest expense	3,788	1,580	7,581	3,197
Interest income	(942)	—	(1,708)	—
Other expense (income), net	121	(21)	(584)	268
Loss before income taxes	(70,373)	(65,682)	(137,964)	(127,671)
Income tax expense	195	88	508	233
Net loss	$ (70,568)	$ (65,770)	$ (138,472)	$ (127,904)
Net loss per common share — basic and diluted	$ (0.79)	$ (0.99)	$ (1.68)	$ (1.97)
Weighted average common shares outstanding — basic and diluted	88,798,398	66,666,876	82,667,061	64,997,698

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

Research and development	$ 3,618	$ 1,846	$ 6,166	$ 3,407
General and administrative	$ 4,313	$ 2,879	$ 8,217	$ 5,562

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

	September 30, 2019	**March 31, 2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 130,373	$ 156,074
Marketable securities	27,220	—
Prepaid expenses and other current assets	9,969	10,194
Income tax receivable	17	524
Total current assets	167,579	166,792
Property and equipment, net	2,288	2,071
Operating lease right-of-use asset	8,973	—
Other assets	5,162	4,114
Total assets	$ 184,002	$ 172,977

Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 5,819	$ 11,019
Interest payable	305	1,077
Accrued expenses	44,380	53,614
Operating lease liability	853	—
Due to Roivant Sciences Ltd., Roivant Sciences, Inc., and Roivant Sciences GmbH	271	121
Current maturities of long-term debt	8,402	6,142
Total current liabilities	60,030	71,973
Deferred rent	—	1,157
Deferred interest payable	5,323	2,273
Long-term operating lease liability	9,320	—
Long-term debt, less current maturities	92,075	93,240
Total liabilities	166,748	168,643
Total shareholders' equity	17,254	4,334
Total liabilities and shareholders' equity	$ 184,002	$ 172,977

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SOURCE: Myovant Sciences

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