



Myovant Sciences Provides Recent Corporate Updates and Reports Financial Results for Third Fiscal Quarter Ended December 31, 2019

February 10, 2020

- **96.7% response rate in Phase 3 HERO study support submission of New Drug Application (NDA) for relugolix monotherapy tablet for advanced prostate cancer in the second quarter of calendar year 2020**
- **87.7% one-year response rate in LIBERTY open-label extension study supports submission of NDA for relugolix combination tablet for women with heavy menstrual bleeding associated with uterine fibroids in April 2020**
- **Enrollment completed in Phase 3 SPIRIT 2 and SPIRIT 1 studies in women with pain associated with endometriosis with top-line results expected in the first and second quarters of calendar year 2020, respectively**
- **Closed low-interest loan facility from Sumitomo Dainippon Pharma of \$400 million**

BASEL, Switzerland, Feb. 10, 2020 (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 third fiscal quarter ended December 31, 2019.

"The next six months promise to be an inflection point for Myovant as we expect to submit NDAs for prostate cancer and uterine fibroids in the U.S. and announce data from two Phase 3 studies in endometriosis," said Lynn Seely, M.D., CEO of Myovant. "We are preparing to potentially bring two distinct one pill, once-a-day treatments to the many women and men who suffer from these common diseases. The low-interest loan facility from Sumitomo Dainippon Pharma strengthens our financial position and further supports this vision."

Third Fiscal Quarter 2019 and Recent Business Highlights

Relugolix Phase 3 Clinical Programs

- In November 2019, Myovant announced that the Phase 3 HERO study evaluating the safety and efficacy of once-daily, oral relugolix monotherapy (120 mg) over 48 weeks in 934 men with advanced prostate cancer met its primary efficacy endpoint with a 96.7% response rate and all tested key secondary endpoints, while demonstrating 54% fewer major cardiovascular events as compared with leuprolide injections administered every three months. Myovant anticipates submitting its NDA for relugolix monotherapy tablet for men with advanced prostate cancer in the second quarter of calendar year 2020.
- In February 2020, Myovant announced positive one-year safety and efficacy data from the LIBERTY open-label extension study with an 87.7% response rate and, on average, an 89.9% reduction in menstrual blood loss from baseline, while demonstrating maintenance of bone mineral density through one year consistent with LIBERTY 1 and 2. Myovant expects to submit its NDA for relugolix combination tablet for women with heavy menstrual bleeding associated with uterine fibroids in April 2020. The NDA submission, for which Myovant no longer expects to use a priority review voucher, will include complete one-year safety and efficacy data from the LIBERTY open-label extension study, key data that may positively impact the labeled duration of use of the relugolix combination tablet. Myovant also anticipates submitting a Marketing Authorization Application (MAA) to the European Medicines Agency in the first quarter of calendar year 2020.
- Myovant completed patient recruitment in SPIRIT 2 in August 2019 and in SPIRIT 1 in October 2019, enrolling 623 women and 638 women, respectively. The SPIRIT 1 and 2 are replicate Phase 3 studies evaluating the safety and efficacy of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) 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.
- In December 2019, Myovant successfully completed one-year stability studies for the relugolix combination tablet in support of potential commercialization.

Corporate

- In December 2019, Myovant Sciences transferred a majority of Myovant's outstanding common shares to Sumitovant Biopharma Ltd. (Sumitovant), a subsidiary of Sumitomo Dainippon Pharma. Concurrent with the transfer of these shares, Myovant entered into a low interest (3-month LIBOR plus 3%) revolving loan facility of up to \$400 million with Sumitomo Dainippon Pharma. In addition, Hiroshi Nomura, Representative Director, President and CEO of Sumitomo Dainippon Pharma, and Adele Gulfo, Chief Business and Commercial Development Officer at Sumitovant, joined Myovant's Board of Directors.
- In December 2019, Myovant used initial proceeds of \$113.7 million from the Sumitomo Dainippon Pharma loan facility to repay all of Myovant's outstanding obligations to NovaQuest Capital Management (NovaQuest) and Hercules Capital, Inc.

(Hercules).

- In December 2019, Myovant announced the promotion of Frank Karbe to President and Chief Financial Officer and Matthew Lang to Chief Administrative and Legal Officer.

Third Fiscal Quarter 2019 Financial Summary

Research and development (R&D) expenses for the quarter ended December 31, 2019, were \$48.9 million compared to \$58.4 million for the comparable prior year period. R&D expenses in both periods 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 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 combination tablet and relugolix monotherapy tablet in multiple indications and jurisdictions, as well as increases in personnel expenses, share-based compensation expense, and other R&D expenses. For the quarter ended December 31, 2019, 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 the transaction between Roivant and Sumitomo Dainippon Pharma.

General and administrative (G&A) expenses for the quarter ended December 31, 2019, were \$29.1 million compared to \$10.7 million for the comparable prior year period. The increase primarily reflects a one-off increase in share-based compensation, as well as increases in personnel-related expenses, professional service fees, expenses related to commercial operations activities in advance of potential regulatory approvals of relugolix combination tablet and relugolix monotherapy tablet, other general overhead and administrative expenses to support Myovant's headcount growth and expanding operations and the assumption of activities previously provided by Myovant's former majority shareholder, Roivant. For the quarter ended December 31, 2019, G&A expenses include \$14.4 million of share-based compensation, of which \$10.2 million are related to the accelerated vesting of certain equity awards as a result of a change in control in Myovant.

Interest expense for the quarter ended December 31, 2019, was \$3.6 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 arrangements with NovaQuest and Hercules. On December 31, 2019, Myovant repaid all of its outstanding obligations to NovaQuest and Hercules.

Loss on extinguishment of debt for the quarter ended December 31, 2019, 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 comparable prior year period.

Interest income for the quarter ended December 31, 2019, was \$0.6 million. There was no interest income for the quarter ended December 31, 2018. During the quarter ended December 31, 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 December 31, 2019, was \$85.6 million, compared to \$70.6 million for the comparable prior year period. The increase in the net loss for the quarter was driven primarily by the increase in expenses outlined above. On a per common share basis, net loss was \$0.96 and \$1.04 for the quarters ended December 31, 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 \$98.9 million as of December 31, 2019. As of December 31, 2019, Myovant had \$286.3 million of available borrowing capacity under the loan facility from Sumitomo Dainippon Pharma. Additional funds may be drawn down by Myovant no more than once any calendar quarter, subject to certain terms and conditions, including consent of Myovant's Board of Directors.

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 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 pain associated 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 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. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma, is the majority shareholder of Myovant. For more information, please visit the company's website at www.myovant.com. Follow [@Myovant](https://twitter.com/Myovant) on Twitter and [LinkedIn](https://www.linkedin.com/company/myovant).

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' aspirations to become the leading healthcare company focused on innovative treatments for women's health and prostate cancer, Myovant Sciences' plans and expected timing to submit regulatory filings for relugolix combination tablet and relugolix monotherapy tablet in the U.S. and Europe and Myovant's plans to announce top-line results from ongoing clinical trials; and the potential for the LIBERTY open-label extension study data to positively impact the labeled duration of use. 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 on November 12, 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 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 December 31,		Nine Months Ended December 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development ⁽¹⁾	\$ 48,927	\$ 58,434	\$ 150,847	\$ 163,588
General and administrative ⁽¹⁾	29,142	10,686	59,897	29,738
Total operating expenses	78,069	69,120	210,744	193,326
Interest expense	3,641	1,634	11,222	4,831
Loss on extinguishment of debt	4,851	—	4,851	—
Interest expense (related party)	16	—	16	—
Interest income	(597))	(2,305))
Other (income) expense, net	(567)) (121) (1,151) 147
Loss before income taxes	(85,413) (70,633) (223,377) (198,304
Income tax expense	191	—	699	233
Net loss	\$ (85,604) \$ (70,633) \$ (224,076) \$ (198,537
Net loss per common share — basic and diluted	\$ (0.96) \$ (1.04) \$ (2.64) \$ (3.01
Weighted average common shares outstanding — basic and diluted	88,893,579	67,616,419	84,750,114	65,873,779

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

Research and development ⁽²⁾	\$ 5,399	\$ 1,840	\$ 11,565	\$ 5,247
General and administrative ⁽³⁾	\$ 14,396	\$ 2,954	\$ 22,613	\$ 8,516

⁽²⁾ For the three and nine months ended December 31, 2019, 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 three and nine months ended December 31, 2019, 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)

December 31, 2019 March 31, 2019

Assets

Current assets:		
Cash and cash equivalents	\$ 83,073	\$ 156,074
Marketable securities	15,815	—
Prepaid expenses and other current assets	12,086	10,194
Income tax receivable	—	524
Total current assets	110,974	166,792
Property and equipment, net	2,406	2,071
Operating lease right-of-use asset	11,491	—
Other assets	4,636	4,114
Total assets	\$ 129,507	\$ 172,977
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	\$ 6,617	\$ 11,019
Interest payable	—	1,077
Interest payable (related party)	16	—
Accrued expenses	45,214	53,735
Operating lease liability	1,449	—
Current maturities of long-term debt	—	6,142
Total current liabilities	53,296	71,973
Deferred rent	—	1,157
Deferred interest payable	—	2,273
Long-term operating lease liability	11,399	—
Long-term debt, less current maturities	—	93,240
Long-term debt, less current maturities (related party)	113,700	—
Total liabilities	178,395	168,643
Total shareholders' (deficit) equity	(48,888) 4,334
Total liabilities and shareholders' (deficit) equity	\$ 129,507	\$ 172,977

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SOURCE: Myovant Sciences



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