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

August 6, 2019

-Positive results from both Phase 3 LIBERTY trials and bioequivalence study supports submission of NDA for uterine fibroids which is expected by year end 2019 and MAA which is expected by Q1-2020-

-Top-line data from Phase 3 HERO trial in advanced prostate cancer expected by year end 2019 with Phase 3 SPIRIT data in endometriosis expected in Q1 and Q2 2020-

BASEL, Switzerland, Aug. 06, 2019 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: **MYOV**), a clinical-stage healthcare company focused on developing and commercializing innovative therapies for women's health and prostate cancer, today announced recent corporate updates and reported financial results for the first fiscal quarter ended June 30, 2019.

"Myovant Sciences recently announced positive top-line data for the LIBERTY 1 and LIBERTY 2 studies evaluating relugolix combination therapy in women with uterine fibroids, as well as the positive results from a separate bioequivalence study supporting a potential one pill, once-a-day dosing regimen of relugolix combination therapy," said Lynn Seely, M.D., President and Chief Executive Officer of Myovant Sciences. "These results confirm the potential of relugolix to offer a constellation of attributes in a single pill, taken once-a-day and we are now focused on preparing for the New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA), which we plan to file by the end of this calendar year. We also look forward to reporting data from our Phase 3 prostate cancer study later this calendar year and results from our two Phase 3 endometriosis studies in the first and second quarters of calendar year 2020."

First Fiscal Quarter 2019 and Recent Business Highlights

Relugolix Phase 3 Clinical Programs

- On May 14, 2019, Myovant Sciences announced positive top-line results from the LIBERTY 1 Phase 3 study evaluating relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) once-a-day in women with uterine fibroids and heavy menstrual bleeding. The study met its primary endpoint with a p-value of <0.0001 and achieved six key secondary endpoints with a well-tolerated safety profile.

- On July 23, 2019, Myovant Sciences announced positive top-line results from the LIBERTY 2 Phase 3 study evaluating relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding. This study also met its primary endpoint with a p-value of <0.0001 and achieved six key secondary endpoints with a well-tolerated safety profile.

- On July 23, 2019, Myovant Sciences also announced that the single-tablet relugolix combination therapy met all required FDA criteria in a separate bioequivalence study supporting a potential one-pill, once-a-day dosing regimen of relugolix.

- Based on the positive top-line results for LIBERTY 1 and LIBERTY 2, Myovant Sciences currently plans to submit an NDA for one-pill, once-a-day relugolix combination therapy for the treatment of heavy menstrual bleeding and uterine fibroids to the FDA in the fourth quarter of calendar year 2019 and the Marketing Authorisation Application to the European Medicines Agency in the first quarter of calendar year 2020.

- Enrollment of approximately 130 additional men with metastatic prostate cancer in the Phase 3 HERO study was completed in July 2019. The objective of enrolling these men was 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.

MVT-602 Clinical Program

- Myovant Sciences completed a successful dose-finding pharmacokinetic/pharmacodynamic Phase 2a study of MVT-602, a kisspeptin-1 receptor agonist, in healthy women undergoing a minimal controlled ovarian stimulation protocol. Top-line results were presented at the European Society of Human Reproduction in Vienna, Austria in June 2019. The study demonstrated that MVT-602 was generally well-tolerated and produced the desired luteinizing hormone surge associated with high and dose-dependent rates of ovulation in healthy women following a minimal controlled ovarian stimulation protocol.

Corporate

- On June 4, 2019, Myovant Sciences completed an underwritten public equity offering, receiving net proceeds of

approximately $134.5 million.

- In the first quarter of fiscal year 2019, Myovant Sciences received aggregate net proceeds of $2.5 million pursuant to the issuance of common shares under its “at-the-market” equity offering program.

First Fiscal Quarter 2019 Financial Summary

Research and development (R&D) expenses for the quarter ended June 30, 2019, were $51.1 million compared to $51.3 million for the comparable prior year period. The composition of R&D expenses in both periods is similar, and primarily includes expenses related to Myovant Sciences’ Phase 3 clinical studies as well as personnel-related expenses for employees engaged in R&D activities. R&D expenses for the quarter ended June 30, 2018 reflected a ramp up in relugolix Phase 3 study costs primarily related to study enrollment, whereas R&D expenses for the quarter ended June 30, 2019 reflect lower relugolix Phase 3 study costs as certain studies are in the process of winding down. The decrease in relugolix Phase 3 study costs were partially offset by increases in other R&D spending related to Myovant Sciences’ preparations to seek regulatory approval for its product candidates.

General and administrative (G&A) expenses for the quarter ended June 30, 2019, were $14.2 million compared to $8.7 million for the comparable prior year period. The increase primarily reflects increases in personnel-related expenses, professional service fees, share-based compensation, and other general overhead and administrative expenses to support Myovant Sciences’ headcount growth and expanding operations.

Interest expense for the quarter ended June 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 the financing agreements as compared to the prior year period.

Interest income for the quarter ended June 30, 2019, was $0.8 million. There was no interest income for the quarter ended June 30, 2018. During the quarter ended June 30, 2019, a portion of Myovant Sciences’ cash was invested in a combination of money market funds and commercial paper. There were no such investments during the prior year period.

Net loss for the quarter ended June 30, 2019, was $67.9 million, compared to $62.1 million for the comparable prior year period. On a per common share basis, net loss was $0.89 and $0.98 for the quarters ended June 30, 2019, and 2018, respectively. The increase in the net loss for the quarter was driven primarily by the increase in costs outlined above.

Capital resources: Cash and cash equivalents totaled $226.7 million as of June 30, 2019. During the quarter ended June 30, 2019, Myovant Sciences raised net proceeds of approximately $134.5 million from an underwritten public equity offering and approximately $2.5 million from its “at-the-market” equity offering program. Myovant Sciences currently has approximately $10.4 million of capacity available under the “at-the-market” equity offering program that it initiated in April 2018.

About Relugolix

Relugolix is a once-a-day, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces ovarian estradiol and progesterone production, hormones known to stimulate uterine fibroids and endometriosis. Myovant Sciences has successfully completed two Phase 3 clinical studies (LIBERTY 1 and LIBERTY 2) evaluating relugolix combination therapy (relugolix 40 mg plus 1.0 mg estradiol with 0.5 mg norethindrone acetate) in women with heavy menstrual bleeding and uterine fibroids and is studying relugolix combination therapy in two Phase 3 clinical studies (SPIRIT 1 and SPIRIT 2) in women with endometriosis-associated pain. Data from SPIRIT 2 and SPIRIT 1 are expected in the first and second quarters, respectively, of calendar year 2020. Relugolix also lowers testosterone in men, an androgen known to drive the growth of prostate cancer. Myovant Sciences is evaluating relugolix, 120 mg once-a-day, in the Phase 3 HERO study in men with advanced prostate cancer. Top-line results from the HERO study are expected in the fourth quarter of calendar year 2019.

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. Myovant Sciences’ lead product candidate is relugolix, an oral, once-a-day small molecule that acts as a GnRH receptor antagonist. Myovant Sciences has three late-stage clinical programs for relugolix ongoing in uterine fibroids, endometriosis and prostate cancer. Myovant Sciences 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 granted Myovant Sciences 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. Over time, Myovant Sciences intends to expand its development pipeline to include other potential treatments for women’s health and prostate cancer. For more information, please visit Myovant Sciences’ website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn (https://linkedin.com/company/myovant-sciences/).

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, Myovant Sciences’ intentions to expand its development pipeline to include other potential treatments for women’s health and prostate cancer, Myovant Sciences’ plans to submit the uterine fibroids NDA to the FDA in the fourth quarter of calendar year

2019 and the Marketing Authorisation Application to the European Medicines Agency in the first quarter of calendar year 2020, to report data from its Phase 3 prostate cancer study later this calendar year and the results from its two Phase 3 endometriosis studies in the first and second quarters of calendar year 2020.

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' Annual Report on Form 10-K filed with the SEC on May 24, 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 August 6, 2019, as such risk factors may be amended, supplemented or superseded from time to time by other reports Myovant Sciences files with the SEC. 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 June 30,	
	2019	**2018**
Operating expenses:		
Research and development [1]	$ 51,117	$ 51,341
General and administrative [1]	14,152	8,742
Total operating expenses	65,269	60,083
Interest expense	3,793	1,617
Interest income	(766)	—
Other (income) expense, net	(705)	289
Loss before income taxes	(67,591)	(61,989)
Income tax expense	313	145
Net loss	$ (67,904)	$ (62,134)
Net loss per common share — basic and diluted	$ (0.89)	$ (0.98)
Weighted average common shares outstanding — basic and diluted	76,468,347	63,310,177
(1) Includes the following share-based compensation expenses:		
Research and development	$ 2,548	$ 1,561
General and administrative	$ 3,904	$ 2,683

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

	June 30, 2019	**March 31, 2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 226,734	$ 156,074
Prepaid expenses and other current assets	8,693	10,194
Income tax receivable	331	524
Total current assets	235,758	166,792
Property and equipment, net	2,057	2,071
Operating lease right-of-use asset	9,181	—
Other assets	3,877	4,114
Total assets	$ 250,873	$ 172,977
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 10,004	$ 11,019
Interest payable	758	1,077
Accrued expenses	46,258	53,614
Operating lease liability	813	—
Due to Roivant Sciences Ltd., Roivant Sciences, Inc., and Roivant Sciences GmbH	196	121

Current maturities of long-term debt	10,867	6,142
Total current liabilities	68,896	71,973
Deferred rent	—	1,157
Deferred interest payable	3,790	2,273
Long-term operating lease liability	9,550	—
Long-term debt, less current maturities	89,070	93,240
Total liabilities	171,306	168,643
Total shareholders' equity	79,567	4,334
Total liabilities and shareholders' equity	$ 250,873	$ 172,977

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SOURCE: Myovant Sciences

Source: Myovant Sciences, Inc.