Myovant Sciences Provides Corporate Update and Reports Financial Results for First Fiscal Quarter Ended June 30, 2017

August 10, 2017

- Initiated three Phase 3 clinical programs for relugolix spanning five trials in first half 2017- Strengthened senior management team with four key hires- Expecting Phase 3 data from Takeda from two trials for relugolix in Japanese women with uterine fibroids in second half of 2017

BASEL, Switzerland, Aug. 10, 2017 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV), a leading clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health and endocrine diseases, today announced corporate updates and reported financial results for the first fiscal quarter ended June 30, 2017.

"Following our successful IPO, we built an accomplished team and rapidly initiated three Phase 3 clinical development programs for relugolix in the first half of 2017," stated Lynn Seely, MD, President and Chief Executive Officer of Myovant Sciences. "I am incredibly proud that our recently formed company was able to achieve our ambitious goal of launching five Phase 3 international clinical trials: two in women suffering from uterine fibroids, two in women with endometriosis-associated pain, and one in men with advanced prostate cancer. We are now looking forward to data coming in 2017 from two Phase 3 trials conducted by Takeda evaluating relugolix in Japanese women with uterine fibroids."

Recent Business Progress

Successfully initiated three Phase 3 programs in the first half of 2017. In June 2017, Myovant announced the initiation of a Phase 3 clinical program consisting of two randomized, double-blind, placebo-controlled, international clinical trials, SPIRIT 1 and SPIRIT 2, to evaluate relugolix in women with endometriosis-associated pain. Each of the two clinical trials is expected to enroll approximately 600 women aged 18 to 50 years with a diagnosis of endometriosis confirmed by laparoscopy or laparotomy. This follows the initiation in January 2017 of a Phase 3 clinical program consisting of two trials, LIBERTY 1 and LIBERTY 2, with an aggregate of approximately 780 women enrolled, to evaluate relugolix in women with heavy menstrual bleeding associated with uterine fibroids, as well as the initiation in March 2017 of a large international Phase 3 clinical trial, HERO, with approximately 1,125 men expected to enroll, to evaluate relugolix in men with advanced prostate cancer.

Significant presence at several medical meetings. In May 2017, positive data were presented from a Takeda-sponsored Phase 2 study at the annual meeting of the American Congress of Obstetricians and Gynecologists demonstrating that treatment with relugolix resulted in a significant decrease in blood loss in Japanese women with heavy menstrual bleeding and uterine fibroids as compared with those receiving placebo ($p < 0.0003$). Also in May 2017, positive data were presented from a Takeda-sponsored Phase 2 trial of relugolix in Japanese women with endometriosis-associated pain during an oral presentation at the World Congress on Endometriosis. The study met its primary endpoint by demonstrating statistically significant dose-dependent reductions over placebo in each of three study arms on the change from baseline in overall pelvic pain at the end of the 12-week treatment period, with the greatest decline in overall pelvic pain observed in the relugolix 40-mg group ($p < 0.0001$ vs. placebo). Data were also presented at the European Congress of Endocrinology in May 2017 from a Phase 2 extension study sponsored by Takeda to evaluate relugolix in women with endometriosis-associated pain over a 6-month period. Efficacy outcomes for the full 24-week period were consistent with outcomes during the initial 12-week trial, with greater dose-dependent reductions in overall pelvic pain, dysmenorrhea, and non-menstrual pelvic pain observed in the relugolix treatment arms compared to placebo. Relugolix was generally well tolerated in each of the studies described above, including during the 24 weeks comprising the initial 12-week study and the 12-week extension treatment in women with endometriosis. Treatment-emergent adverse events for patients receiving relugolix, such as hot flush and menorrhagia, and bone mineral density loss assessed by bone densitometry, were consistent with relugolix's mechanism of action.

Strengthened senior management team through four key hires. In July 2017, Juan Camilo Arjona Ferreira, MD, joined Myovant as Chief Medical Officer; Matthew Lang, JD, joined as General Counsel and Corporate Secretary; Teresa Perney, PhD, joined as Senior Vice President of Regulatory Affairs and Quality Assurance; and Andria Langenberg, MD, joined as Head of Drug Safety and Pharmacovigilance.

Upcoming Milestones

Top-line results from two Phase 3 trials conducted by Takeda anticipated in the second half of 2017. Takeda is conducting a Phase 3 non-inferiority trial of relugolix compared with leuprolide in women with heavy menstrual bleeding from uterine fibroids and a second Phase 3 placebo-controlled trial evaluating women with pain symptoms from uterine fibroids. Data from both Phase 3 trials are expected to be released in the second half of 2017. These trials were designed to support marketing approval of relugolix in Japan and will be available to Myovant for use as potentially supportive data for approvals in the U.S. and other regions.

First Fiscal Quarter 2017 Financial Summary

Research and development (R&D) expenses for the quarter ended June 30, 2017 were $17.7 million, compared to $14.6 million for the comparable period in 2016. The increase was primarily due to higher clinical trial costs related to the ramp up of LIBERTY 1 and LIBERTY 2, the ramp up of HERO,

and the initiation of SPIRIT 1 and SPIRIT 2. R&D expenses for the quarter ended June 30, 2016 consisted primarily of in-process research and development expenses of $13.1 million, which were related to Myovant's acquisition of the rights to its product candidates from Takeda.

General and administrative (G&A) expenses for the quarter ended June 30, 2017 were $4.2 million, compared to $2.6 million for the same period in 2016. The increase was primarily due to increased personnel expenses to support Myovant's rapidly expanding activities. A substantial portion ($1.3 million) of the G&A expenses in the quarter ended June 30, 2017 was attributable to non-cash, share-based compensation expense.

Net loss for the quarter ended June 30, 2017 was $23.3 million, or $0.39 per share, compared to $19.0 million or $0.47 per share for the same period in 2016. The increase in net loss was primarily due to increases in operating expenses, partially off-set by a decrease in the change in the fair value of the Takeda warrant, which expired on April 30, 2017.

Cash totaled $154.2 million on June 30, 2017.

About Relugolix

Relugolix is an oral, once-daily, small molecule that acts as a GnRH receptor antagonist and has been evaluated in over 1,300 study participants in Phase 1 and multiple large controlled Phase 2 clinical trials. In these trials, relugolix has been shown to be generally well tolerated and to suppress estrogen and progesterone levels in women and testosterone levels in men. Common side effects are consistent with suppression of these hormones. In the Phase 3 SPIRIT clinical trials in women with endometriosis-associated pain and the Phase 3 LIBERTY clinical trials in women with heavy menstrual bleeding associated with uterine fibroids, relugolix will be evaluated with and without low-dose hormonal add-back therapy, the addition of which is expected to decrease potential side effects such as bone mineral density loss and hot flashes.

About Myovant Sciences

Myovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for women's health and endocrine diseases. Myovant's lead product candidate is relugolix, an oral, once-daily, small molecule that acts as a GnRH receptor antagonist. Myovant has initiated three clinical programs for relugolix consisting of five international Phase 3 clinical trials, two in women with heavy menstrual bleeding associated with uterine fibroids, two in women with endometriosis-associated pain, and one in men with advanced prostate cancer. Myovant is simultaneously developing MVT- 602, a kisspeptin agonist, for the treatment of female infertility as part of assisted reproduction. Over time, the company intends to expand its development pipeline to include other potential treatments for women's health and endocrine diseases. For more information, please visit the company's website at myovant.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Takeda's anticipated Phase 3 data announcement and Myovant's ability to advance the clinical development of its lead product candidate, relugolix, and expand its development pipeline. Forward-looking statements can be identified by the words "believe," "anticipate," "continue", "estimate", "project," "expect," "plan," "potential," "intends," "will," "would", "could", "should" or the negative or plural of these words or other similar expressions that are predictions or indicate future events, trends or prospects. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the fact that Takeda's anticipated data announcement is not within Myovant's control; risks associated with the success, cost and timing of our product development activities and clinical trials; the approval and commercialization of our product candidates relugolix and MVT-602; and increased regulatory requirements. These statements are subject to the risk that clinical trial data are subject to differing interpretations, and regulatory agencies, medical and scientific experts and others may not share Myovant's views of the clinical study data. There can be no assurance that the clinical programs for relugolix or MVT-602 will be successful in demonstrating safety and/or efficacy, that we will not encounter problems or delays in clinical development, or that any of our product candidates will ever receive regulatory approval or be successfully commercialized. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Myovant's business in general, see the "Risk Factors" section of our quarterly report on Form 10-Q to be filed with the Securities and Exchange Commission on or about August 10, 2017, and other filings that Myovant makes with the SEC from time to time. These forward-looking statements are based on information available to Myovant as of the date of this press release and speak only as of the date of this release. Myovant disclaims any obligation to update these forward-looking statements, except as may be required by law.

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Condensed Consolidated Statements of Operations

(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended June 30, 2017	**Three Months Ended June 30, 2016**
Operating expenses:		
Research and development (includes $860 and $975 of share-based compensation expense for the three months ended June 30, 2017 and 2016, respectively)	$ 17,708	$ 14,573
General and administrative (includes $1,341 and $1,646 of share-based compensation expense for the three months ended June 30, 2017 and 2016, respectively)	4,182	2,562

Total operating expenses	21,890	17,135
Changes in the fair value of the warrant liability	—	1,832
Other expense	342	—
Loss before provision for income taxes	(22,232)	(18,967)
Income tax expense	1,085	3
Net loss	$ (23,317)	$ (18,970)
Net loss per common share — basic and diluted	$ (0.39)	$ (0.47)
Weighted average common shares outstanding — basic and diluted	59,247,273	40,771,548

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Condensed Consolidated Balance Sheets

(Unaudited, in thousands)

	June 30, 2017	**March 31, 2017**
Assets		
Current assets:		
Cash	$ 154,191	$ 180,838
Prepaid expenses and other current assets	5,182	3,221
Income tax receivable	—	105
Total current assets	159,373	184,164
Deferred tax assets	—	208
Property and equipment, net	952	906
Other assets	3,074	—
Total assets	$ 163,399	$ 185,278
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 3,186	$ 3,329
Income tax payable	721	—

Accrued expenses	11,292	11,978
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	2,000	3,030
Total current liabilities	17,199	18,337
Warrant liability	—	52
Deferred rent	218	113
Total liabilities	17,417	18,502
Total shareholders' equity	145,982	166,776
Total liabilities and shareholders' equity	$ 163,399	$ 185,278

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