



## Myovant Provides Corporate Updates and Reports Financial Results for Third Fiscal Quarter Ended December 31, 2018

February 7, 2019

BASEL, Switzerland, Feb. 7, 2019 /PRNewswire/ -- Myovant Sciences (NYSE: MYOV), a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of women's health and endocrine diseases, today announced corporate updates and reported financial results for the third fiscal quarter ended December 31, 2018.

"As we enter this new year, we look forward to our first Phase 3 data from our LIBERTY program in uterine fibroids. The recent approval by Takeda for Relumina® (relugolix 40 mg tablets) for the treatment of uterine fibroids in Japan, further validates our belief in relugolix as a critical treatment for people with uterine fibroids in the U.S. and Europe," said Lynn Seely, M.D., President and Chief Executive Officer of Myovant Sciences. "We continue to be on track to deliver data from both our LIBERTY and HERO programs this year, however enrollment for our SPIRIT endometriosis studies has taken longer than anticipated. While we remain confident that enrollment will be completed in 2019, we now anticipate top-line data for SPIRIT will be available in the first quarter of next year."

### **Recent Business Highlights and Upcoming Milestones**

#### *Relugolix Phase 3 Clinical Programs*

- Completed patient enrollment in the Phase 3 LIBERTY 2 trial evaluating relugolix in combination with estradiol and a progestin in women with heavy menstrual bleeding associated with uterine fibroids.
- Expect top-line data from LIBERTY 1 and LIBERTY 2 Phase 3 trials evaluating the safety and efficacy of relugolix in combination with estradiol and a progestin in women with heavy menstrual bleeding associated with uterine fibroids in Q2 and Q3 of 2019, respectively, and assuming positive data, submission of the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in Q4 of 2019.
- Expect top-line data from the HERO Phase 3 trial evaluating the safety and efficacy of relugolix in men with advanced prostate cancer in Q4 2019, and assuming positive data, submission of the NDA to the FDA in early 2020.
- Expect completion of enrollment in both SPIRIT 1 and SPIRIT 2 Phase 3 trials evaluating the safety and efficacy of relugolix in women with pain associated with endometriosis this year, with top-line data expected in Q1 2020.
- On January 8, 2019, Takeda Pharmaceutical Company Limited and ASKA Pharmaceutical Co., Ltd. announced that Takeda has obtained marketing authorization in Japan from the Ministry of Health, Labour and Welfare for Relumina® Tablets 40 mg (generic name: relugolix) for the improvement of symptoms of uterine fibroids (heavy menstrual bleeding, lower abdominal pain, lower back pain, and anemia).

#### *MVT-602 Clinical Program*

- Completed enrollment in the dose-finding pharmacokinetic/pharmacodynamic Phase 2a study of MVT-602, a kisspeptin-1 receptor agonist, in healthy women undergoing a controlled ovarian stimulation protocol. Top-line results are expected to be reported in the first half of 2019.

#### *Corporate*

- Raised proceeds of \$92.0 million pursuant to our existing financing arrangement with NovaQuest in late December 2018.

### **Third Fiscal Quarter 2018 Financial Summary**

**Research and development (R&D)** expenses for the quarter ended December 31, 2018, were \$58.4 million compared to \$34.9 million for the comparable period in 2017. The increase for the quarter primarily reflects the progress of Myovant's ongoing Phase 3 clinical trials of relugolix, which were initiated in 2017, as well as additional personnel-related expenses and MVT-602 clinical trial expenses.

**General and administrative (G&A)** expenses for the quarter ended December 31, 2018, were \$10.7 million compared to \$6.6 million for the comparable period in 2017. The increase for the quarter primarily reflects increases in personnel-related expenses, professional service fees, and other administrative expenses to support Myovant's headcount growth and expanding operations.

**Net interest expense** for the quarter ended December 31, 2018, was \$1.6 million compared to \$0.9 million in the comparable prior year period. Net interest expense consists of interest expense related to financing agreements with NovaQuest and Hercules Capital, Inc., as well as the associated non-cash amortization of debt discount and issuance costs, partially offset by interest income earned on cash equivalents.

**Net loss** for the quarter ended December 31, 2018, was \$70.6 million, compared to \$41.8 million for the comparable period in 2017. On a per common share basis, net loss was \$1.04 and \$0.70 for the quarters ended December 31, 2018, and 2017, respectively. The increases in the net loss and net loss per common share for the quarter were driven primarily by the increase in costs outlined above.

**Capital resources:** Cash and cash equivalents totaled \$183.0 million at December 31, 2018. An additional \$40.6 million of capacity remains available

under the "at-the-market" equity offering program that Myovant initiated in April 2018.

### **About Relugolix**

Relugolix is an oral, once-daily, small molecule that acts as a gonadotropin-releasing hormone, or GnRH, receptor antagonist. More than 2,150 study participants have received treatment with relugolix in Phase 1, Phase 2 and Phase 3 clinical trials. In completed trials, relugolix was generally well tolerated and suppressed estrogen and progesterone levels in women and testosterone levels in men. Common side effects observed were consistent with suppression of these hormones.

In the ongoing Phase 3 LIBERTY clinical trials in women with heavy menstrual bleeding associated with uterine fibroids and the ongoing Phase 3 SPIRIT clinical trials in women with pain associated with endometriosis, relugolix is undergoing evaluation in combination with estradiol and norethindrone acetate, a progestin, and as monotherapy. Myovant is studying whether the combination optimizes estradiol levels to the range required to treat the signs and symptoms of endometriosis and uterine fibroids while minimizing the side effects associated with low estrogen levels, which include bone mineral density loss and hot flashes. The ongoing Phase 3 HERO study is evaluating relugolix monotherapy 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 trial in healthy female volunteers to characterize the dose-response curve in the controlled ovarian stimulation setting has completed enrollment.

### **About Myovant Sciences**

Myovant Sciences is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for the treatment of 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 (LIBERTY 1 & 2), two in women with pain associated with endometriosis (SPIRIT 1 & 2), and one in men with advanced prostate cancer (HERO). Myovant is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, that is in Phase 2a development for the treatment of female infertility as part of assisted reproduction. Takeda Pharmaceuticals International AG granted Myovant an exclusive, worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries where Takeda retains exclusive rights) and an exclusive license to develop and commercialize MVT-602 in all countries worldwide. Over time, Myovant intends to expand its development pipeline to include other potential treatments for women's health and endocrine diseases. For more information, please visit Myovant's website at [www.myovant.com](http://www.myovant.com).

### **Forward-Looking Statements**

This press-release contains forward-looking statements, including without limitation, statements related to: Myovant's focus on developing and commercializing innovative therapies for the treatment of women's health and endocrine diseases and its intent to expand its development pipeline to include other potential treatments for women's health and endocrine diseases; the statements and Dr. Seely's quotes regarding the expected timelines for announcing patient enrollment and top-line safety and efficacy data for relugolix in 2019 and 2020 in three distinct indications; other statements relating to the timing of reporting clinical trial results, including the expected timeline for top-line results of the Phase 2a study of MVT-602 in the first half of 2019; and the announcement by Takeda that it has obtained marketing authorization in Japan from the Ministry of Health, Labour and Welfare for Relumina® (Relugolix 40 mg Tablets) for the improvement of symptoms of uterine fibroids (heavy menstrual bleeding, lower abdominal pain, lower back pain, and anemia) and Dr. Seely's quote that the marketing authorization further validates our belief in relugolix as a critical treatment for people with uterine fibroids in the U.S. and Europe. Forward-looking statements can be identified by words such as "anticipate," "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. Myovant 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. Such forward-looking statements 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. Factors that could cause or contribute to such differences include, but are not limited to, risks relating to those discussed in the section titled "Risk Factors" set forth in Part II, Item 1A of Myovant's Quarterly Report on Form 10-Q filed with the United States Securities and Exchange Commission, or the SEC, on November 8, 2018, and in Myovant's future filings with the SEC including without limitation, Myovant's Quarterly Report on Form 10-Q expected to be filed with the SEC on or about February 7, 2019, and other filings that Myovant makes with the SEC from time to time. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for its management to predict all risk factors, nor can Myovant 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. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, Myovant undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

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### **MYOVANT SCIENCES LTD.**

### **Condensed Consolidated Statements of Operations**

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

	<b>Three Months Ended December 31, Nine Months Ended December 31,</b>			
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
Operating expenses:				
Research and development <sup>(1)</sup>	\$ 58,434	\$ 34,875	\$ 163,588	\$ 76,753
General and administrative <sup>(2)</sup>	10,686	6,640	29,738	16,963
Total operating expenses	69,120	41,515	193,326	93,716
Interest expense, net	1,634	904	4,831	904
Other (income) expense, net	(121)	(429)	147	(225)
Loss before income taxes	(70,633)	(41,990)	(198,304)	(94,395)
Income tax (benefit) expense	—	(213)	233	607
Net loss	\$ (70,633)	\$ (41,777)	\$ (198,537)	\$ (95,002)
Net loss per common share — basic and diluted	\$ (1.04)	\$ (0.70)	\$ (3.01)	\$ (1.60)
Weighted average common shares outstanding—basic and diluted	67,616,419	59,629,486	65,873,779	59,446,140

<sup>(1)</sup> Includes the following share-based compensation expense:

Research and development	\$ 1,840	\$ 1,041	\$ 5,247	\$ 2,580
General and administrative	\$ 2,954	\$ 2,252	\$ 8,516	\$ 5,663

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**Condensed Consolidated Balance Sheets**

(Unaudited, in thousands)

**December 31, 2018    March 31, 2018**

**Assets**

Current assets:

Cash and cash equivalents	\$ 183,003	\$ 108,624
Prepaid expenses and other current assets	12,396	5,139

Income tax receivable	767	1,000
Total current assets	196,166	114,763
Property and equipment, net	1,693	1,273
Other assets	3,811	3,065
Total assets	\$ 201,670	\$ 119,101

**Liabilities and Shareholders' Equity**

Current liabilities:

Accounts payable	\$ 5,471	\$ 4,578
Interest payable	429	282
Accrued expenses	48,388	30,265
Due to RSL, RSI and RSG	66	1,960
Current maturities of long-term debt	1,520	—
Total current liabilities	55,874	37,085
Deferred rent	1,132	408
Deferred interest payable	773	255
Long-term debt, less current maturities	97,156	43,624
Total liabilities	154,935	81,372
Total shareholders' equity	46,735	37,729
Total liabilities and shareholders' equity	\$ 201,670	\$ 119,101

SOURCE Myovant Sciences