Myovant Sciences Announces Corporate Updates and Financial Results for Fourth Fiscal Quarter and Fiscal Year Ended March 31, 2021

May 11, 2021

- *Fourth fiscal quarter 2020 total revenues of $24.6 million; net product revenue from sales of ORGOVYX in the U.S. of $3.6 million*
- *FDA review of New Drug Application for relugolix combination tablet for uterine fibroids remains on track for a decision by June 1, 2021 target action date; U.S. launch expected in June 2021, if approved*
- *Remain on track to submit U.S. regulatory filing for endometriosis in the second quarter of calendar year 2021*
- *European Commission decision on uterine fibroids Marketing Authorization Application remains on track for mid-calendar year 2021; Gedeon Richter to launch and commercialize, if approved*
- *European Medicines Agency validated Marketing Authorization Application for relugolix for the treatment of advanced prostate cancer*
- *Reported positive data for relugolix combination therapy from Phase 3 SPIRIT extension study in women with endometriosis and from Phase 3 LIBERTY randomized withdrawal study in women with uterine fibroids*
- *Company remains well-capitalized with cash, cash equivalents, marketable securities and committed funding of $726.2 million as of March 31, 2021*

BASEL, Switzerland, May 11, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced corporate updates and financial results for the fourth fiscal quarter and fiscal year ended March 31, 2021.

“The ORGOVYX launch is off to a strong start and its differentiated clinical profile has the potential to redefine care for men with advanced prostate cancer. ORGOVYX demand accelerated over the course of the quarter, reflecting our ongoing efforts to educate urologists and medical oncologists about ORGOVYX while improving access and reimbursement for patients. In partnership with Pfizer, we continue to execute on our long-term goal of establishing ORGOVYX as the new standard of care androgen deprivation therapy,” said David Marek, Chief Executive Officer of Myovant Sciences, Inc. “I am also pleased with the progress we have made in preparing for the U.S. launch of relugolix combination tablet in women with uterine fibroids, which is expected this June. In addition, we have advanced relugolix combination tablet toward a U.S. regulatory submission in endometriosis and our European regulatory submission for relugolix monotherapy for the treatment of advanced prostate cancer was validated by the European Medicines Agency.”

Fourth Fiscal Quarter 2020 and Recent Corporate Updates

ORGOVYX

- ORGOVYX was launched in the U.S. and authorized specialty distribution channels were fully stocked in early January 2021. Fourth fiscal quarter 2020 net product revenues for ORGOVYX in the U.S. were $3.6 million.
- More than 800 treatment centers have prescribed ORGOVYX to over 2,000 patients, estimated through April 30, 2021.
- Through April 30, 2021, Myovant achieved 43% commercial coverage and 51% Medicare Part D coverage for ORGOVYX. Myovant continues to engage in coverage negotiations with key commercial and Medicare Part D payors and remains on track to achieve its goal of broad coverage at the end of calendar year 2021.

Relugolix Monotherapy

- On March 29, 2021, Myovant announced that the European Medicines Agency (EMA) validated its Marketing Authorization Application (MAA) for relugolix for the treatment of advanced prostate cancer. The validation of the application confirmed that the submission is sufficiently complete for the EMA to begin the review process.

Relugolix Combination Tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg)

- ***Uterine Fibroids***
    - On March 24, 2021, Myovant and Pfizer announced positive safety and efficacy data from the Phase 3 LIBERTY randomized withdrawal study in women with uterine fibroids. The study met its primary endpoint and all three key secondary endpoints. Bone mineral density was maintained through two years in the subset of women continuously treated with relugolix combination therapy (N = 31). The incidence of adverse events over one additional year of treatment was consistent with those observed in prior studies, with no new safety signals observed.

- ***Endometriosis***
    - On January 26, 2021, Myovant and Pfizer announced that the Phase 3 SPIRIT long-term extension study in women with endometriosis reported clinically meaningful reductions in dysmenorrhea (menstrual pain) and non-menstrual pelvic pain over one year with minimal and stable bone mineral density loss. The data are consistent with the efficacy and safety profile observed through 24 weeks in the Phase 3 SPIRIT 1 and SPIRIT 2 studies. These results will be included in the regulatory submission to the U.S. Food and Drug Administration (FDA) for relugolix combination tablet for the treatment of women with endometriosis, expected in the second quarter of calendar year 2021.
- ***Prevention of Pregnancy***
    - On April 12, 2021, Myovant and Pfizer announced that the first patient was dosed in the Phase 3 SERENE study evaluating the contraceptive efficacy of relugolix combination tablet in healthy women ages 18-35 years who are at risk for pregnancy. The SERENE study is designed to enroll 900 sexually active, healthy women ages 18-35 years with presumed normal fertility. The primary efficacy endpoint is the at-risk Pearl Index, defined as the number of on-treatment pregnancies per 100 women-years of treatment. Safety data will also be collected during the study. Results of the SERENE study could support a potential indication of pregnancy prevention for women treated with relugolix combination tablet, if approved.

Executive Appointments

- On January 4, 2021, Myovant announced the appointment of David Marek as Chief Executive Officer of Myovant Sciences, Inc. Concurrent with this appointment, Mr. Marek was also appointed Principal Executive Officer of Myovant Sciences Ltd. and a member of its Board of Directors.
- On April 5, 2021, Myovant announced the appointment of Lauren Merendino as Chief Commercial Officer of Myovant Sciences, Inc. Ms. Merendino is also a member of Myovant's Executive Committee.

Expected Upcoming Milestones

- FDA decision for relugolix combination tablet for the treatment of uterine fibroids is expected by the June 1, 2021 target action date. If approved, Myovant and Pfizer expect to launch in the U.S. in June 2021. Upon FDA approval, Myovant will receive a $100.0 million regulatory milestone payment from Pfizer.
- U.S. regulatory submission to the FDA for relugolix combination tablet for the treatment of women with endometriosis-associated pain is expected in the second quarter of calendar year 2021.
- Pfizer's decision regarding its exclusive option to acquire development and commercialization rights to relugolix in oncology outside of the U.S. and Canada (excluding certain Asian markets) is expected in mid-calendar year 2021. If Pfizer exercises this option, Myovant will receive a $50.0 million payment and will be eligible to receive double-digit royalties on net sales.
- European Commission (EC) decision on the uterine fibroids MAA is expected in mid-calendar year 2021. If approved, this launch will be executed by Gedeon Richter Plc. (Richter), Myovant's commercialization partner for relugolix combination tablet for the uterine fibroids and endometriosis indications in Europe and certain other international markets.
- MAA submission to the EMA for relugolix combination tablet for the treatment of women with endometriosis-associated pain is expected in calendar year 2021. Richter will be the MAA sponsor.
- EC decision on the advanced prostate cancer MAA is expected in calendar year 2022.

Fourth Fiscal Quarter and Fiscal Year Ended March 31, 2021 Financial Summary

Total revenues for the three months and year ended March 31, 2021, were $24.6 million and $59.3 million, respectively. There were no revenues recorded in the comparable prior year periods.

- **Product revenue, net** from sales of ORGOVYX in the U.S. for the three months and year ended March 31, 2021 were $3.6 million.
- **Collaboration revenue** for the three months and year ended March 31, 2021 was $21.0 million and $22.4 million, respectively, and represents partial amortization of the upfront payment received from Pfizer pursuant to the Pfizer Collaboration and License Agreement.
- **License and milestone revenue** for the year ended March 31, 2021 was $33.3 million and represents the partial

recognition of revenue associated with the $40.0 million upfront payment and a $10.0 million regulatory milestone payment received from Richter under the Richter Development and Commercialization Agreement.

Cost of product revenue for the three months and year ended March 31, 2021, was $0.3 million related to the cost of goods sold and royalty expense payable to Takeda pursuant to the Takeda License Agreement. There were no such expenses for the comparable prior year periods.

Collaboration expense to Pfizer for the three months and year ended March 31, 2021, was $1.7 million, reflecting Pfizer's 50% share of net profits from sales of ORGOVYX in the U.S., pursuant to the Pfizer Collaboration and License Agreement. There were no such expenses for the comparable prior year periods.

Research and development (R&D) expenses for the three months ended March 31, 2021, were $21.6 million compared to $41.7 million for the comparable prior year period. R&D expenses for the year ended March 31, 2021, were $136.7 million compared to $192.6 million for the prior fiscal year. The decrease in R&D expenses reflects a reduction in clinical study costs as a result of the wind down of Myovant's Phase 3 LIBERTY, HERO, and SPIRIT studies and cost share reimbursements from Pfizer for certain R&D expenses in the fiscal 2020 periods. This decrease was partially offset primarily by an increase in personnel expenses, mainly driven by the continued expansion of Myovant's medical affairs organization to support the U.S. commercial launch of ORGOVYX and the potential U.S. commercial launches of relugolix combination tablet for the women's health indications, if approved, as well as regulatory expenses and incremental spend on new relugolix development programs.

Selling, general and administrative (SG&A) expenses for the three months ended March 31, 2021, were $78.0 million compared to $22.4 million for the comparable prior year period. SG&A expenses in the year ended March 31, 2021, were $181.4 million compared to $82.3 million for the prior fiscal year. The increase was primarily due to higher expenses related to commercial activities to support the ORGOVYX U.S. launch and commercial readiness activities for the potential U.S. launch of relugolix combination tablet, higher personnel-related costs primarily due to the hiring of Myovant's commercial operations, marketing, and market access teams, as well as the oncology sales force, higher share-based compensation expense, and general overhead expenses to support Myovant's organizational growth. Share-based compensation expense for the three months and year ended March 31, 2021 includes incremental expense of $25.7 million related to the acceleration, modification, and remeasurement of our former Principal Executive Officer's outstanding equity awards. SG&A expenses for the year ended March 31, 2020 included $10.2 million in share-based compensation expense related to the accelerated vesting of certain equity awards as well as a $3.6 million capital tax accrual.

Interest expense was $3.5 million for the three months ended March 31, 2021, compared to $1.4 million for the comparable prior year period. Interest expense was $10.4 million for the year ended March 31, 2021, compared to $12.7 million for the prior fiscal year. The decrease in interest expense, despite higher outstanding loan balances, was primarily driven by the significantly lower interest rates associated with the Sumitomo Dainippon Pharma Loan Agreement as compared to Myovant's previously outstanding debt obligations, which were repaid in December 2019.

There was no **loss on extinguishment of debt** for the year ended March 31, 2021. For the year ended March 31, 2020, Myovant recorded a $4.9 million loss resulting from the early repayment of Myovant's previously outstanding debt obligations in December 2019.

Interest income for the three months ended March 31, 2021, was less than $0.1 million compared to $0.2 million for the comparable prior year period. Interest income for the year ended March 31, 2021, was $0.2 million compared to $2.6 million for the prior fiscal year. The decrease was primarily due to decreases in interest rates.

Foreign exchange loss (gain) for the three months ended March 31, 2021, was a loss of less than $0.1 million compared to a gain of $0.5 million for the comparable prior year period. Foreign exchange gain for the year ended March 31, 2021, was $16.2 million compared to $1.6 million for the prior fiscal year. The increase for the year ended March 31, 2021 was primarily due to a larger foreign currency exchange gain on Myovant's outstanding balance under the Sumitomo Dainippon Pharma Loan Agreement during the year ended March 31, 2021 compared to the prior year.

Net loss for the three months ended March 31, 2021, was $81.4 million compared to $64.9 million for the comparable prior year period. Net loss for the year ended March 31, 2021, was $255.1 million compared to $289.0 million for the prior fiscal year. On a per common share basis, net loss was $0.89 and $0.73 for the three months ended March 31, 2021 and 2020, respectively, and $2.83 and $3.37 for the year ended March 31, 2021 and 2020, respectively.

Capital resources: Cash, cash equivalents, marketable securities, and amounts available under the Sumitomo Dainippon Pharma Loan Agreement totaled $726.2 million as of March 31, 2021, and consisted of $684.9 million of cash, cash equivalents, and marketable securities and $41.3 million of available borrowing capacity under the Sumitomo Dainippon Pharma Loan Agreement.

Conference Call

As previously announced, Myovant will hold a webcast and conference call at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) today, May 11, 2021, to discuss corporate updates and financial results for its fourth fiscal quarter and fiscal year ended March 31, 2021. Investors and the general public may access a live webcast of the call by visiting the investor relations page of Myovant's website at investors.myovant.com. Institutional investors and analysts may also participate in the conference call by dialing 1-800-532-3746 in the U.S. or +1-470-495-9166 from outside the U.S. The webcast will be archived on Myovant's Investor Relations website following the call.

About Relugolix

Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces testicular testosterone, a hormone known to stimulate the growth of prostate cancer, and ovarian estradiol, a hormone known to stimulate the growth of uterine fibroids and endometriosis. Relugolix monotherapy (120 mg) is FDA-approved as ORGOVYX™ for the treatment of adult patients with advanced prostate cancer and is under regulatory review in Europe for the treatment of men with advanced prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review in the U.S. and Europe for women with uterine fibroids, has completed Phase 3 registration-enabling studies for women with endometriosis, and is being assessed for contraceptive efficacy in healthy women ages 18-35 years who are at risk for pregnancy.

About Myovant Sciences

Myovant Sciences (Myovant) aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. ORGOVYX™ (relugolix) was approved by the FDA in 2020 as the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist for the treatment of adult patients with advanced prostate cancer, and relugolix is also under regulatory review in Europe

for men with advanced prostate cancer. Myovant's lead product candidate, relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), is under regulatory review in the U.S. and Europe for women with uterine fibroids, has completed Phase 3 registration-enabling studies for women with endometriosis, and is being assessed for contraceptive efficacy in healthy women ages 18-35 years who are at risk for pregnancy. Myovant is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for female infertility as part of assisted reproduction. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is Myovant's majority shareholder. For more information, please visit Myovant's website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn.

About Sumitomo Dainippon Pharma Co., Ltd.
Sumitomo Dainippon Pharma is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including the U.S., Japan, 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.

About Sumitovant Biopharma Ltd.
Sumitovant is a global biopharmaceutical company with offices in New York City and London. Sumitovant is the majority shareholder of Myovant, and wholly owns Urovant Sciences, Enzyvant Therapeutics, Spirovant Sciences, and Altavant Sciences. Sumitovant's pipeline is comprised of commercialized and investigational medicines across a range of disease areas targeting high unmet need. Sumitovant is a wholly owned subsidiary of Sumitomo Dainippon Pharma. For further information about Sumitovant, please visit https://www.sumitovant.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In this press release, forward-looking statements include, but are not limited to, all statements reflecting Myovant Sciences' expectations, including: statements regarding Myovant's aspiration to redefine care for women and for men; certain statements with respect to expectations of commercialization of ORGOVYX in Mr. Marek's quote; Myovant's expectations regarding status of its publicly announced milestones; Myovant's expected timelines of coverage decisions by commercial and Medicare Part D payors; the timing of Myovant's regulatory submissions, anticipated regulatory review results, and U.S. launch of relugolix combination tablet in women with uterine fibroids; the design and any expectation of the results of the SERENE study; and those statements under the caption "Expected Upcoming Milestones."

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, including unforeseen circumstances or other disruptions to normal business operations arising from or related to the COVID-19 pandemic. 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 to be filed on May 11, 2021, 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 March 31,		Year Ended March 31,	
	2021	2020	2021	2020
Revenues:				
Product revenue, net	$ 3,630	$ —	$ 3,630	$ —
Collaboration revenue	20,975	—	22,354	—
License and milestone revenue	—	—	33,333	—
Total revenues	24,605	—	59,317	—
Operating costs and expenses:				
Cost of product revenue	301	—	301	—
Collaboration expense to Pfizer	1,664	—	1,664	—
Research and development [(1)]	21,553	41,713	136,713	192,560
Selling, general and administrative [(1)]	78,036	22,430	181,423	82,327
Total operating costs and expenses	101,554	64,143	320,101	274,887
Loss from operations	(76,949)	(64,143)	(260,784)	(274,887)
Interest expense	3,493	1,425	10,401	12,663
Loss on extinguishment of debt	—	—	—	4,851
Interest income	(33)	(247)	(211)	(2,552)

Foreign exchange loss (gain)	2	(470)	(16,176)	(1,621)
Loss before income taxes	(80,411)	(64,851)	(254,798)	(288,228)
Income tax expense	952	62	336	761
Net loss	$ (81,363)	$ (64,913)	$ (255,134)	$ (288,989)
Net loss per common share — basic and diluted	$ (0.89)	$ (0.73)	$ (2.83)	$ (3.37)
Weighted average common shares outstanding — basic and diluted	91,018,204	89,130,806	90,036,459	85,839,303

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

Research and development	$ 2,989	$ 2,959	$ 14,049	$ 14,524
Selling, general and administrative	28,941	3,114	39,627	25,727
Total share-based compensation expense	$ 31,930	$ 6,073	$ 53,676	$ 40,251

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

	March 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 674,493	$ 76,644
Accounts receivable, net	3,570	—
Marketable securities	10,435	2,997
Inventory	2,611	—
Prepaid expenses and other current assets	13,536	8,269
Total current assets	704,645	87,910
Property and equipment, net	3,300	2,497
Operating lease right-of-use asset	9,655	11,146
Other assets	7,427	4,373
Total assets	$ 725,027	$ 105,926
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 17,809	$ 15,334
Accrued expenses and other current liabilities	44,612	29,060
Share-based compensation liabilities	21,636	—
Deferred revenue	100,564	40,000
Amounts due to collaboration partner	1,954	—
Cost share advance from collaboration partner	92,415	—
Operating lease liability	1,807	1,516
Amounts due to related parties	543	15
Total current liabilities	281,340	85,925
Deferred revenue, non-current	397,369	—
Cost share advance from collaboration partner, non-current	29,447	—
Long-term operating lease liability	9,189	10,996
Long-term debt, less current maturities (related party)	358,700	113,700
Other	2,947	3,582
Total liabilities	1,078,992	214,203
Total shareholders' deficit	(353,965)	(108,277)
Total liabilities and shareholders' deficit	$ 725,027	$ 105,926

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