Myovant Sciences Announces Financial Results for Second Quarter of Fiscal Year 2021 and Corporate Updates

October 26, 2021

- *Second fiscal quarter 2021 total revenues of $77.9 million; net product revenue from U.S. sales of ORGOVYX® of $18.7 million and MYFEMBREE® of $0.6 million*
- *Estimated 8,000 cumulative patients treated with ORGOVYX through September 2021, including patients on commercial and free drug; Approximately 600 cumulative patients treated with MYFEMBREE through September 2021 including patients on commercial drug and free drug programs, excluding patients utilizing product samples*
- *MYFEMBREE supplemental New Drug Application for the management of moderate to severe pain associated with endometriosis accepted for review by FDA in September 2021; FDA target action date is May 6, 2022*
- *RYEQO® approved in the European Union and United Kingdom; Gedeon Richter launched RYEQO in seven countries*
- *Phase 3 SERENE study evaluating MYFEMBREE for the prevention of pregnancy resumed in August 2021 following study protocol amendments; initial patients dosed in October 2021*
- *Assessing partnership opportunities with multiple interested parties for international rights to relugolix in oncology following Pfizer's decision to decline its option based on their assessment of their current strategic investment priorities in international markets; no impact to collaboration in U.S. and Canada*
- *Myovant remains well-capitalized with cash, cash equivalents, marketable securities, and committed funding of $657.3 million as of September 30, 2021*

BASEL, Switzerland, Oct. 26, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced financial results for the second quarter of fiscal year 2021 and other corporate updates.

"During our second fiscal quarter, we continued to make significant progress on the commercial launches of ORGOVYX and MYFEMBREE, enabling our mission to redefine care and positioning Myovant for long-term success. ORGOVYX launch momentum continued to build with net product revenues of $18.7 million, representing 78% sequential growth compared to the previous quarter, and reflecting increased patient and clinician demand for the differentiated clinical profile of ORGOVYX. Our team remains passionate about improving the lives of men with advanced prostate cancer by providing the first and only approved oral medication capable of rapidly and profoundly reducing testosterone levels without an initial hormonal surge," said David Marek, Chief Executive Officer of Myovant Sciences, Inc.

Mr. Marek added, "We are also encouraged by the early launch progress for MYFEMBREE as we bring this important new treatment option to women in the U.S. with symptomatic uterine fibroids. Sequential growth since launch across key metrics, including cumulative patients on therapy and enrollments to the MYFEMBREE patient support hub, coupled with increasing prescriber awareness and recent improvements in payer coverage gives us confidence that MYFEMBREE is being positioned for long-term success. Additionally, the FDA in August lifted the partial clinical hold on the Phase 3 SERENE study following certain protocol amendments, and in September, accepted our supplemental New Drug Application seeking to extend approval of MYFEMBREE to include women with endometriosis, with a decision expected by May 6, 2022."

Second Fiscal Quarter 2021 and Recent Corporate Updates

ORGOVYX (relugolix 120 mg)

- Second fiscal quarter 2021 net product revenues for ORGOVYX in the U.S. were $18.7 million, driven by increased prescriber demand.
- Approximately 1,500 treatment centers have prescribed ORGOVYX to approximately 8,000 patients on free and commercial drug, estimated through September 30, 2021. The cumulative number of estimated patients initiating ORGOVYX therapy has continued to increase steadily in each successive month since launch.
- As of October 1, 2021, Myovant achieved 76% commercial coverage and 81% Medicare Part D coverage for ORGOVYX. Myovant achieved broad coverage for ORGOVYX in advance of its calendar year-end 2021 goal but continues to engage in negotiations with payors yet to make a coverage decision. Myovant expects broad commercial and Part D coverage for ORGOVYX to continue in calendar-year 2022.

MYFEMBREE (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg)

- Second fiscal quarter 2021 net product revenues for MYFEMBREE in the U.S. were $0.6 million, primarily reflecting a

continuation of initial inventory stocking. Modest demand-driven re-orders to replenish launch inventories began in September 2021.

- Approximately 600 patients have initiated treatment through September 30, 2021, including patients on commercial drug and free drug programs, excluding patients utilizing product samples.
- As of October 8, 2021, Myovant achieved 61% commercial coverage for MYFEMBREE. Myovant continues to engage in coverage negotiations with key commercial payors yet to make a coverage decision and remains on track to achieve its goal of broad coverage within one year of launch.
- In October 2021, Myovant and Pfizer presented data from clinical studies of MYFEMBREE at the American Society for Reproductive Medicine (ASRM) 2021 Congress, including results of the Phase 3 LIBERTY randomized withdrawal study, which was designed to evaluate the efficacy and safety of relugolix combination therapy for up to two years in women with heavy menstrual bleeding associated with uterine fibroids, and was designated an ASRM Prize Paper. Additional data presentations at ASRM included data from the SPIRIT 1 and 2 studies of women with pain associated with endometriosis as well as pooled safety and tolerability data from the LIBERTY and SPIRIT clinical programs.
- In September 2021, the U.S. Food and Drug Administration (FDA) accepted Myovant's supplemental New Drug Application (sNDA) for MYFEMBREE for the management of moderate to severe pain associated with endometriosis, setting a target action date of May 6, 2022. FDA approval of MYFEMBREE for this indication would trigger a $100.0 million regulatory milestone payment from Pfizer.
- In August 2021, the FDA informed Myovant that the partial clinical hold for the Phase 3 SERENE study evaluating MYFEMBREE for the prevention of pregnancy was lifted following study protocol amendments. The amended SERENE study protocol will evaluate the contraceptive efficacy of MYFEMBREE in women with heavy menstrual bleeding associated with uterine fibroids or endometriosis-associated pain who are 18 to 50 years of age and at risk for pregnancy, and includes bone mineral density monitoring for patients during and after treatment. Patient screening with this updated protocol began in September 2021, with initial patients dosed in October 2021.
- The FDA approval of MYFEMBREE in May 2021 for the management of heavy menstrual bleeding associated with uterine fibroids in the U.S. triggered a $100.0 million regulatory milestone payment from Pfizer, which Myovant received in July 2021.

RYEQO (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg)

- On July 16, 2021 and August 9, 2021, the European Commission (EC) and the Medicines and Healthcare products Regulatory Agency, respectively, approved RYEQO for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. RYEQO is the first and only long-term, once-daily oral treatment for uterine fibroids with no limitation on its duration of use approved in the European Union and the United Kingdom. Gedeon Richter (Richter), Myovant's commercialization partner for RYEQO in Europe and certain other international markets, launched RYEQO in seven countries since these regulatory approvals.
- The approval of RYEQO for the uterine fibroids indication by the EC triggered a $15.0 million regulatory milestone payment from Richter, which Myovant received and recorded as Richter license and milestone revenue in its second fiscal quarter of 2021.

Pfizer Option

- On October 22, 2021, Myovant was notified by Pfizer of their decision to decline the exclusive option for international commercialization and development rights (excluding Canada and certain Asian countries) to relugolix in oncology, as offered under the December 2020 collaboration agreement between the two companies. Pfizer's decision is based on their assessment of their current strategic investment priorities in international markets and does not impact the companies' collaboration in the U.S. and Canada for ORGOVYX and MYFEMBREE. Myovant is currently assessing partnership opportunities with multiple interested parties, focusing on potential partners with a European commercial presence in urology or oncology.

Executive Appointments

- On September 7, 2021, Uneek Mehra was appointed Chief Financial and Business Officer of Myovant Sciences, Inc. Concurrent with this appointment, Mr. Mehra was also appointed Principal Financial Officer of Myovant Sciences Ltd.

Expected Upcoming Milestones

- FDA submission of the Phase 3 LIBERTY randomized withdrawal study results for MYFEMBREE in women with uterine

fibroids is expected by the end of calendar year 2021 or in the first quarter of calendar year 2022.

- Two-year data from the SPIRIT long-term extension study of MYFEMBREE in women with endometriosis-associated pain is expected in the first quarter of calendar year 2022.
- FDA decision for the MYFEMBREE sNDA seeking approval for the management of moderate to severe pain associated with endometriosis is expected by its May 6, 2022 target action date. FDA approval of MYFEMBREE for this indication would trigger a $100.0 million regulatory milestone payment from Pfizer.
- EC decision on the advanced prostate cancer Marketing Authorisation Application is expected in mid-calendar year 2022.
- European Medicines Agency regulatory submission for RYEQO for the treatment of women with endometriosis-associated pain is expected in calendar year 2022. Richter will be the sponsor.

Second Fiscal Quarter 2021 Financial Summary

Total revenues for the three months ended September 30, 2021 were $77.9 million. There were no such revenues in the three months ended September 30, 2020.

- **Product revenue, net** from sales of ORGOVYX and MYFEMBREE in the U.S. for the three months ended September 30, 2021 were $18.7 million and $0.6 million, respectively. For the three months ended September 30, 2021 product revenue, net also includes revenues related to product supply to Richter of $1.7 million, as well as royalties on net sales of RYEQO in Richter's Territory of less than $0.1 million. There was no such revenue recorded in the comparable prior year period.
- **Pfizer collaboration revenue** for the three months ended September 30, 2021 was $25.2 million, reflecting the partial recognition of the upfront payment Myovant received from Pfizer in December 2020 and of the regulatory milestone payment that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids in May 2021. There was no such revenue recorded in the comparable prior year period.
- **Richter license and milestone revenue** for the three months ended September 30, 2021 was $31.7 million, reflecting recognition of the remaining $16.7 million of previously deferred revenue as a result of Myovant's delivery of the remaining substantive relugolix combination tablet data packages to Richter pursuant to the Richter Development and Commercialization Agreement, and the $15.0 million regulatory milestone payment triggered by the EC approval of RYEQO for the uterine fibroids indication. There was no such revenue in the three months ended September 30, 2020.

Cost of product revenue for the three months ended September 30, 2021 was $2.6 million related to the cost of goods sold and royalty expense payable to Takeda pursuant to the Takeda License Agreement. There were no such amounts recognized in the comparable prior year period.

Collaboration expense to Pfizer for the three months ended September 30, 2021, was $8.6 million, reflecting Pfizer's 50% share of net profits from sales of ORGOVYX and MYFEMBREE in the U.S., pursuant to the Pfizer Collaboration and License Agreement. There were no such amounts recognized in the comparable prior year period.

Research and development (R&D) expenses for the three months ended September 30, 2021, were $26.3 million compared to $40.5 million for the comparable prior year period. The decrease in R&D expenses reflects cost share reimbursements from Pfizer for certain R&D expenses and a reduction in clinical study costs as a result of the completion and wind down of Myovant's Phase 3 LIBERTY, HERO, and SPIRIT studies. This decrease was partially offset by an increase in medical affairs personnel expenses to support the U.S. launches of ORGOVYX and MYFEMBREE.

Selling, general and administrative (SG&A) expenses for the three months ended September 30, 2021, were $58.8 million compared to $31.3 million for the comparable prior year period. The increase was primarily due to higher expenses to support the ORGOVYX and MYFEMBREE U.S. launches, including higher personnel-related costs primarily due to the hiring of Myovant's commercial operations, marketing, and market access teams, as well as the oncology and women's health sales forces, and higher general overhead expenses to support Myovant's organizational growth.

Interest expense was $3.5 million for the three months ended September 30, 2021, compared to $2.1 million for the comparable prior year period. The increase in interest expense was primarily driven by the higher balance under Myovant's loan agreement with Sumitomo Dainippon Pharma (Sumitomo Dainippon Pharma Loan Agreement) and $0.6 million of accretion of the financing component of the cost share advance from Pfizer.

Foreign exchange gain for the three months ended September 30, 2020 was $6.7 million, primarily the result of the impact of fluctuations in the foreign currency exchange rate between the Swiss franc and the U.S. dollar on Myovant's outstanding balance under the Sumitomo Dainippon Pharma Loan Agreement. As a result of a change in the functional currency of Myovant's wholly-owned subsidiary in Switzerland, Myovant Sciences GmbH, from the Swiss franc to the U.S. dollar in December 2020, Myovant is no longer exposed to significant foreign currency gains or losses.

Net loss for the three months ended September 30, 2021 was $21.6 million compared to $67.1 million for the comparable prior year period. On a per common share basis, net loss was $0.23 and $0.75 for the three months ended September 30, 2021 and 2020, respectively.

Capital resources: Cash, cash equivalents, marketable securities, and amounts available under the Sumitomo Dainippon Pharma Loan Agreement totaled $657.3 million as of September 30, 2021, and consisted of $616.0 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, October 26,

2021, to discuss financial results for its second fiscal quarter ended September 30, 2021 and corporate updates. 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. ORGOVYX® (relugolix 120 mg) was approved in the U.S. by the FDA in December 2020 as the first and only oral GnRH receptor antagonist for the treatment of adult patients with advanced prostate cancer, and relugolix (120 mg) is also under regulatory review in Europe for men with advanced prostate cancer. MYFEMBREE® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) was approved in the U.S. by the FDA in May 2021 as the first and only once-daily oral treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, and by the European Commission and the Medicines and Healthcare products Regulatory Agency in July 2021 and August 2021, respectively, as RYEQO® for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In September 2021, the FDA accepted Myovant Sciences' supplemental New Drug Application for MYFEMBREE for the management of moderate to severe pain associated with endometriosis, setting a target action date of May 6, 2022. MYFEMBREE is also being assessed for contraceptive efficacy in women who are 18 to 50 years of age and at risk for pregnancy.

About Myovant Sciences

Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, Myovant Sciences has two FDA-approved products. ORGOVYX® (relugolix) was approved by the U.S. Food and Drug Administration 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. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) was approved in 2021 in the U.S. as MYFEMBREE® as the first once-daily treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, and by the European Commission and the Medicines and Healthcare products Regulatory Agency as RYEQO® for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Myovant Sciences filed a supplemental New Drug Application for MYFEMBREE for the management of moderate to severe pain associated with endometriosis, which was accepted for review by the FDA in September 2021. MYFEMBREE is also being assessed for the prevention of pregnancy. Myovant Sciences 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 Sciences' majority shareholder. For more information, please visit 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 but not limited to: statements regarding Myovant's aspiration to redefine care for women and for men; Myovant's expectations of the success of commercialization of its approved drug products; Myovant's expectation of broad commercial and Part D coverage for ORGOVYX in calendar-year 2022; the statement that Myovant remains on track to achieve its goal of broad coverage for MYFEMBREE within one year of launch; and the statements under the heading "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' Quarterly Report on Form 10-Q to be filed on October 26, 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 September 30,		Six Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product revenue, net	$ 21,063	$ —	$ 32,617	$ —
Pfizer collaboration revenue	25,172	—	54,681	—
Richter license and milestone revenue	31,667	—	31,667	33,333
Total revenues	77,902	—	118,965	33,333
Operating costs and expenses:				
Cost of product revenue	2,622	—	3,654	—
Collaboration expense to Pfizer	8,565	—	13,826	—
Research and development [(1)]	26,280	40,521	57,160	84,707
Selling, general and administrative [(1)]	58,781	31,316	119,993	54,144
Total operating costs and expenses	96,248	71,837	194,633	138,851
Loss from operations	(18,346)	(71,837)	(75,668)	(105,518)
Interest expense	3,494	2,115	6,999	4,299
Interest income	(100)	(38)	(178)	(146)
Foreign exchange gain	—	(6,718)	—	(10,287)
Loss before income taxes	(21,740)	(67,196)	(82,489)	(99,384)
Income tax (benefit) expense	(149)	(134)	762	538
Net loss	$ (21,591)	$ (67,062)	$ (83,251)	$ (99,922)
Net loss per common share — basic and diluted	$ (0.23)	$ (0.75)	$ (0.90)	$ (1.12)
Weighted average common shares outstanding — basic and diluted	92,355,150	89,744,142	92,019,987	89,523,389
[(1)] Includes the following share-based compensation:				
Research and development	$ 5,060	$ 3,725	$ 9,167	$ 7,749
Selling, general and administrative	6,803	3,199	13,958	6,987
Total share-based compensation expense	$ 11,863	$ 6,924	$ 23,125	$ 14,736
Revenue components are as follows:				
Product revenue, net:				
ORGOVYX	$ 18,663	$ —	$ 29,142	$ —
MYFEMBREE	629	—	1,704	—
Richter product supply and royalties	1,771	—	1,771	—
Total product revenue, net	21,063	—	32,617	—
Pfizer collaboration revenue:				
Amortization of upfront payment	20,974	—	41,948	—
Amortization of regulatory milestone	4,198	—	12,733	—
Total Pfizer collaboration revenue	25,172	—	54,681	—
Richter license and milestone revenue	31,667	—	31,667	33,333
Total revenues	$ 77,902	$ —	$ 118,965	$ 33,333

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

	September 30, 2021	March 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 518,163	$ 674,493
Accounts receivable, net	14,402	3,570
Marketable securities	97,848	10,435
Inventories	6,141	2,611
Prepaid expenses and other current assets	18,112	13,536
Total current assets	654,666	704,645
Property and equipment, net	3,297	3,300
Operating lease right-of-use asset	8,835	9,655
Other assets	12,742	7,427

Total assets	$ 679,540	$ 725,027
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 8,642	$ 17,809
Accrued expenses and other current liabilities	46,334	44,612
Share-based compensation liabilities	5,769	21,636
Deferred revenue	100,564	100,564
Amounts due to Pfizer	19,957	1,954
Cost share advance from Pfizer	84,768	92,415
Operating lease liability	1,968	1,807
Amounts due to related parties	334	543
Total current liabilities	268,336	281,340
Deferred revenue, non-current	426,021	397,369
Cost share advance from Pfizer, non-current	—	29,447
Long-term operating lease liability	8,159	9,189
Long-term debt, less current maturities (related party)	358,700	358,700
Other liabilities	1,251	2,947
Total liabilities	1,062,467	1,078,992
Total shareholders' deficit	(382,927)	(353,965)
Total liabilities and shareholders' deficit	$ 679,540	$ 725,027

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