Myovant Sciences Announces Corporate Updates and Financial Results for First Fiscal Quarter 2022

July 27, 2022

- *First fiscal quarter 2022 total revenue of $116.5 million, including net product revenue of $41.4 million*
- *Net product revenue from U.S. sales of ORGOVYX® of $36.0 million in first fiscal quarter 2022, with sequential quarterly demand volume growth of 26% and cumulative patients estimated at 18,000 through June 2022*
- *Net product revenue from U.S. sales of MYFEMBREE® of $4.0 million in first fiscal quarter 2022, with sequential quarterly demand volume growth of 54%*
- *MYFEMBREE remains the number one prescribed FDA-approved gonadotropin-releasing hormone (GnRH) antagonist therapy for the treatment of uterine fibroids for new patients and is now the market leader in total prescriptions (TRx) with 51% TRx share in June 2022*
- *FDA provided labeling comments with respect to the MYFEMBREE supplemental New Drug Application (sNDA) for the management of moderate to severe pain associated with endometriosis; on track for a decision by its August 6, 2022 target action date*
- *FDA accepted sNDA proposing updates to MYFEMBREE's U.S. Prescribing Information based on 2-year data from the Phase 3 LIBERTY randomized withdrawal study; set target action date of January 29, 2023*
- *Myovant remains well-capitalized with cash, cash equivalents, marketable securities, and committed financing of $400.0 million as of June 30, 2022*

BASEL, Switzerland, July 27, 2022 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a biopharmaceutical company that aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy, today announced financial results for the first quarter of fiscal year 2022 and provided other corporate updates.

"We're excited to start fiscal year 2022 with solid performance across both brands," said David Marek, Chief Executive Officer of Myovant Sciences, Inc. "ORGOVYX delivered double digit volume growth across treatment settings and MYFEMBREE is now the market leader in new and total prescriptions while continuing to grow the class." Mr. Marek added, "despite the challenging macro-economic environment, we remain well capitalized to build on our commercial momentum and advance our pipeline in women's health and hormone-sensitive oncology."

First Fiscal Quarter 2022 and Recent Corporate Updates

ORGOVYX (relugolix 120 mg)

- First fiscal quarter 2022 net product revenues for ORGOVYX in the U.S. were $36.0 million, reflecting 22% sequential growth compared to fourth fiscal quarter 2021. ORGOVYX commercial demand volume grew 26% quarter-over-quarter driven by broad adoption and strong growth across all treatment settings.
- Approximately 3,500 new patients started treatment on ORGOVYX in the first fiscal quarter of 2022, reaching approximately 18,000 cumulative patients since launch.
- A $50.0 million upfront payment was received from Accord Healthcare, Ltd. (Accord), pursuant to the exclusive license agreement Myovant entered into with Accord in May 2022 to commercialize ORGOVYX for the treatment of advanced hormone-sensitive prostate cancer in Europe.
- On April 29, 2022, the European Commission (EC), and on June 17, 2022, the United Kingdom (U.K.) Medicines and Healthcare products Regulatory Agency (MHRA), approved ORGOVYX as the first and only oral androgen deprivation therapy for advanced hormone-sensitive prostate cancer in the European Union (EU) and U.K., respectively. We expect our commercialization partner, Accord, to commence the launch of ORGOVYX for the treatment of advanced hormone-sensitive prostate cancer in Europe in the second half of calendar year 2022.

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

- First fiscal quarter 2022 net product revenues for MYFEMBREE in the U.S. were $4.0 million.
- MYFEMBREE maintains market leadership in new-to-brand prescription (NBRx) share among GnRH antagonist therapies approved by the U.S. Food and Drug Administration (FDA) for the treatment of uterine fibroids and is now the number one

prescribed GnRH antagonist therapy for uterine fibroids with 51% total prescription (TRx) share in June 2022. Data provided by Symphony Health.

- Approximately 2,400 new patients started treatment on MYFEMBREE in first fiscal quarter 2022, resulting in 71% sequential quarterly growth in the number of patients treated since launch.
- MYFEMBREE continues to drive total prescription growth of the GnRH antagonist for uterine fibroids class, which has grown 180% since its launch in June 2021, with 61% of MYFEMBREE prescribers being first time prescribers of a GnRH antagonist FDA-approved for the treatment of uterine fibroids.
- FDA provided labeling comments with respect to the MYFEMBREE sNDA for the management of moderate to severe pain associated with endometriosis. FDA's decision is expected by the extended Prescription Drug User Fee Act (PDUFA) goal date of August 6, 2022. An approval would trigger a $100.0 million milestone payment from Pfizer. If approved by the PDUFA goal date, Myovant and Pfizer expect to launch MYFEMBREE in the U.S. for this indication in August 2022.
- In June 2022, the FDA accepted for review an sNDA that proposes updates to MYFEMBREE's U.S. Prescribing Information (USPI) based on 2-year safety and efficacy data from the Phase 3 LIBERTY randomized withdrawal study (RWS) of MYFEMBREE in premenopausal women with heavy menstrual bleeding associated with uterine fibroids. The FDA set a target action date of January 29, 2023 for this sNDA.
- In June 2022, Myovant and Pfizer announced that the results of the Phase 3 SPIRIT 1 and SPIRIT 2 studies of once-daily relugolix combination therapy (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) in women with endometriosis-associated pain were published in *The Lancet*.
- Additional data from the SPIRIT 2-year extension study in women with endometriosis were presented at the European Society of Human Reproduction and Embryology (ESHRE) 2022 Annual Meeting in July 2022. The Society recognized the presentation as the best oral presentation of a clinical topic at the ESHRE 2022 Annual Meeting.

Expected Upcoming Milestones

- Myovant expects the FDA decision for the MYFEMBREE sNDA seeking approval for the management of moderate to severe pain associated with endometriosis by its extended PDUFA goal date of August 6, 2022. Approval would trigger a $100.0 million milestone payment from Pfizer. If approved by the PDUFA goal date, Myovant and Pfizer expect to launch MYFEMBREE in the U.S. for this indication in August 2022.
- European Medicines Agency regulatory submission for RYEQO® for the treatment of women with endometriosis-associated pain is expected in the second half of calendar year 2022. Gedeon Richter Plc. (Richter) will be the sponsor.
- Myovant expects to submit New Drug Submissions to Health Canada seeking marketing approval for ORGOVYX for advanced prostate cancer, MYFEMBREE for heavy menstrual bleeding associated with uterine fibroids, and MYFEMBREE for the treatment of endometriosis-associated pain in Canada in the second half of calendar year 2022.
- Accord is expected to commence the launch of ORGOVYX for the treatment of advanced hormone-sensitive prostate cancer in Europe in the second half of calendar year 2022.
- Myovant expects the FDA decision for the MYFEMBREE sNDA proposing updates to MYFEMBREE's USPI based on the safety and efficacy data from the Phase 3 LIBERTY RWS of MYFEMBREE in premenopausal women with heavy menstrual bleeding associated with uterine fibroids for up to two years by the January 29, 2023 PDUFA goal date.

First Fiscal Quarter 2022 Financial Summary

Total revenues for the three months ended June 30, 2022, and 2021 were $116.5 million and $41.1 million, respectively.

- **Product revenue, net** for the three months ended June 30, 2022 and 2021 were $41.4 million and $11.6 million, respectively. Product revenue, net consisted of the following:
    - Product revenue, net from sales of ORGOVYX in the U.S. for the three months ended June 30, 2022 was $36.0 million compared to $10.5 million for the three months ended June 30, 2021.
    - Product revenue, net from sales of MYFEMBREE in the U.S. for the three months ended June 30, 2022 was $4.0 million compared to $1.1 million for the three months ended June 30, 2021. MYFEMBREE was launched in the U.S in June 2021.
    - Product revenue, net related to product supply to Richter for the three months ended June 30, 2022 was $1.1 million. Product revenue, net related to royalties on net sales of RYEQO in Richter's Territory for the three months

ended June 30, 2022 was $0.2 million. There were no such revenues in the year ago period.

- **Pfizer collaboration revenue** for the three months ended June 30, 2022 and 2021 was $25.1 million and $29.5 million, respectively, reflecting the partial recognition of the upfront payment Myovant received from Pfizer upon entering into the Pfizer Collaboration and License Agreement in December 2020 and of the regulatory milestone payment from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids in May 2021.

- **Accord license revenue** for the three months ended June 30, 2022 was $50.0 million, reflecting the recognition of the upfront payment received from Accord in May 2022 pursuant to the Accord License Agreement. There was no Accord license revenue in the year ago period.

Cost of product revenue for the three months ended June 30, 2022 was $4.9 million, compared to $1.0 million for the three months ended June 30, 2021 related to the cost of goods sold and royalty expense payable to Takeda pursuant to the Takeda License Agreement. The increase in cost of product revenue in the three months ended June 30, 2022 was primarily due to an increase in cost of goods sold and royalty expense payable to Takeda as a result of higher sales of ORGOVYX and MYFEMBREE in the U.S., as compared to the year ago period.

Collaboration expense to Pfizer for the three months ended June 30, 2022, was $18.0 million, compared to $5.3 million for the three months ended June 30, 2021, 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. The increase in collaboration expense to Pfizer in the three months ended June 30, 2022 was due to an increase in net profits generated from sales of ORGOVYX and MYFEMBREE in the U.S., as compared to the year ago period.

Selling, general and administrative (SG&A) expenses for the three months ended June 30, 2022, and 2021 were $79.0 million and $61.2 million, respectively. The increase in SG&A expenses primarily reflects higher expenses to support the ORGOVYX and MYFEMBREE commercialization activities in the U.S, including higher personnel-related costs, patient activation costs particularly for MYFEMBREE, as well as a banker fee associated with the Accord License Agreement.

Research and development (R&D) expenses for the three months ended June 30, 2022, and 2021 were $23.9 million and $30.9 million, respectively. The decrease in R&D expenses primarily reflects a reduction in clinical study costs due to the completion and wind down of Myovant's Phase 3 LIBERTY, HERO, and SPIRIT studies.

Interest expense for the three months ended June 30, 2022, and 2021 was $4.2 million and $3.5 million, respectively, and was primarily related to the Sumitomo Pharma Loan Agreement. Interest expense related to the Sumitomo Pharma Loan Agreement increased $0.7 million, as a result of an increase in 3-month LIBOR as compared to the year ago period. Interest expense includes $0.6 million of accretion of the financing component of the cost share advance from Pfizer for both the three months ended June 30, 2022, and 2021.

Income tax expense for the three months ended June 30, 2022, and 2021 was $8.2 million and $0.9 million, respectively. The increase in income tax expense was driven principally by the changed requirement under Internal Revenue Code Section 174, effective for years beginning after December 31, 2021, to capitalize and subsequently amortize R&D expenditures, pursuant to changes enacted in the Tax Cuts and Jobs Act 2017. For periods beginning prior to December 31, 2021, R&D expenses were allowed to be expensed as incurred.

Net loss for the three months ended June 30, 2022 was $21.2 million compared to $61.7 million for the year ago period. On a per common share basis, net loss was $0.22 and $0.67 for the three months ended June 30, 2022 and 2021, respectively.

Capital resources: Cash, cash equivalents, marketable securities, and amounts available under the Sumitomo Pharma Loan Agreement totaled $400.0 million as of June 30, 2022, and consisted of $358.7 million of cash, cash equivalents, and marketable securities and $41.3 million of available borrowing capacity under the Sumitomo Pharma Loan Agreement.

Conference Call

As previously announced, Myovant will hold a webcast and conference call to discuss corporate updates and financial results for its first fiscal quarter, ended June 30, 2022. The webcast and conference call will be held at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time on July 27, 2022. Investors and the general public may access the live webcast: https://edge.media-server.com/mmc/p/oi3u5djb. The live webcast can also be accessed by visiting the investor relations page of Myovant's website at: https://investors.myovant.com/. A replay of the webcast, along with the earnings press release and presentation materials, can be found on Myovant's investor relations website for a period of one year.

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. In April and June 2022, respectively, the European Commission and the United Kingdom (U.K.) Medicines and Healthcare products Regulatory Agency (MHRA) approved ORGOVYX® (relugolix, 120 mg) as the first and only oral GnRH receptor antagonist for the treatment of adult patients with advanced hormone-sensitive prostate cancer in Europe and the U.K. 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, with a treatment duration of up to 24 months. In July 2021, the European Commission, and in August 2021, the U.K. MHRA, approved RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, with no limitation for duration of use. In September 2021, the FDA accepted to review Myovant's supplemental New Drug Application (sNDA) for MYFEMBREE for the management of moderate to severe pain associated with endometriosis. On May 6, 2022, Myovant and Pfizer announced that the FDA extended the Prescription Drug User Fee Act (PDUFA) goal date for this sNDA to August 6, 2022. In June 2022, the FDA accepted to review Myovant's sNDA for updates to the United States Prescribing Information (USPI) based on safety and efficacy data from the Phase 3 LIBERTY randomized withdrawal study (RWS) of MYFEMBREE in premenopausal women with heavy menstrual bleeding due to uterine fibroids for

up to two years. The FDA set a PDUFA goal date of January 29, 2023 for this sNDA. MYFEMBREE is also being assessed for contraceptive efficacy in women with endometriosis or uterine fibroids 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 has executed five successful Phase 3 clinical trials across oncology and women's health leading to two regulatory approvals by the U.S. Food and Drug Administration (FDA) for men with advanced prostate cancer and women with heavy menstrual bleeding associated with uterine fibroids, respectively. Myovant also has received regulatory approvals by the European Commission (EC) and the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) for women with symptomatic uterine fibroids and for men with advanced hormone-sensitive prostate cancer. Myovant has supplemental New Drug Applications under review with the FDA for endometriosis-associated pain, and for updates to the United States Prescribing Information (USPI) based on safety and efficacy data from the Phase 3 LIBERTY randomized withdrawal study (RWS) of MYFEMBREE in premenopausal women with heavy menstrual bleeding due to uterine fibroids for up to two years. Myovant also is conducting a Phase 3 study to evaluate the prevention of pregnancy in women with uterine fibroids or endometriosis. Myovant also is developing MVT-602, an investigational 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 Pharma Co., Ltd., is Myovant's majority shareholder. For more information, please visit www.myovant.com. Follow @Myovant on Twitter and LinkedIn.

About Sumitovant Biopharma Ltd.

Sumitovant is a global biopharmaceutical company leveraging data-driven insights to rapidly accelerate development of new potential therapies for unmet patient conditions. Through its unique portfolio of wholly-owned "Vant" subsidiaries—Urovant, Enzyvant, Spirovant, Altavant—and use of embedded computational technology platforms to generate business and scientific insights, Sumitovant has supported the development of FDA-approved products and advanced a promising pipeline of early through late-stage investigational assets for other serious conditions. Sumitovant, a wholly-owned subsidiary of Sumitomo Pharma, is also the majority-shareholder of Myovant (NYSE: MYOV). For more information, please visit Sumitovant's website at https://www.sumitovant.com.

About Sumitomo Pharma Co., Ltd.

Sumitomo Pharma is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China, and other Asian countries with more than 7,000 employees worldwide. Sumitomo Pharma defines its corporate mission as "To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide." Additional information about Sumitomo Pharma is available through its corporate website at https://www.sumitomo-pharma.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; Myovant's expectations of the success of commercialization of its approved drug products; statements with respect to Myovant's expectations to remain well capitalized to build on its commercial momentum and advance its pipeline in women's health and hormone-sensitive oncology in Mr. Marek's quote; statements regarding the timing of Myovant's regulatory submissions, anticipated regulatory review results, as well as Myovant's and its collaboration and commercialization partners' expected commercial launches of Myovant's products, including, with no limitations, the timeline and potential outcome of the FDA's review of the MYFEMBREE sNDA for the management of moderate to severe pain associated with endometriosis and if approved by the FDA, the potential milestone payment from Pfizer and the timing and expected launch of MYFEMBREE for this indication; the timeline and potential outcome of the FDA's review of the MYFEMBREE sNDA proposing updates to MYFEMBREE's USPI based on 2-year safety and efficacy data from the Phase 3 LIBERTY RWS of MYFEMBREE in premenopausal women with heavy menstrual bleeding associated with uterine fibroids; the timeline and expectation of launching ORGOVYX for the treatment of advanced hormone-sensitive prostate cancer in Europe by Accord; the timeline and expectation of submitting New Drug Submissions to Health Canada seeking marketing approval for ORGOVYX for advanced prostate cancer, MYFEMBREE for heavy menstrual bleeding associated with uterine fibroids, and MYFEMBREE for the treatment of endometriosis-associated pain in Canada; and other 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 and the conflict in Ukraine. 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 July 27, 2022, 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 and Comprehensive Loss
(Unaudited, in thousands, except share and per share data)

	Three Months Ended June 30,	
	2022	2021
Revenues:		
Product revenue, net	$ 41,351	$ 11,554
Pfizer collaboration revenue	25,141	29,509
Accord license revenue	50,000	—
Total revenues	116,492	41,063
Operating costs and expenses:		
Cost of product revenue[(1)]	4,915	1,032
Collaboration expense to Pfizer	18,016	5,261
Selling, general and administrative[(1)]	79,032	61,212
Research and development[(1)]	23,890	30,880
Total operating costs and expenses	125,853	98,385
Loss from operations	(9,361)	(57,322)
Interest expense	4,200	3,505
Interest income	(486)	(78)
Loss before income taxes	(13,075)	(60,749)
Income tax expense	8,164	911
Net loss and comprehensive loss	$ (21,239)	$ (61,660)
Net loss per common share — basic and diluted	$ (0.22)	$ (0.67)
Weighted average common shares outstanding — basic and diluted	95,388,294	91,637,151

[(1)]Includes the following share-based compensation:

Selling, general and administrative	$ 5,972	$ 7,155
Research and development	3,666	3,957
Cost of product revenue	68	3
Total share-based compensation	$ 9,706	$ 11,115

Revenue components are as follows:

Product revenue, net:		
ORGOVYX	$ 36,034	$ 10,479
MYFEMBREE	3,999	1,075
Richter product supply and royalties	1,318	—
Total product revenue, net	41,351	11,554
Pfizer collaboration revenue:		
Amortization of upfront payment	20,974	20,974
Amortization of regulatory milestone	4,167	8,535
Total Pfizer collaboration revenue	25,141	29,509
Accord license revenue	50,000	—
Total revenues	$ 116,492	$ 41,063

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

	June 30, 2022	March 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 325,535	$ 406,704
Accounts receivable, net	29,648	23,296
Marketable securities	31,216	27,483
Inventories	21,222	7,584
Prepaid expenses and other current assets	18,750	22,498
Amount due from related party	458	580
Total current assets	426,829	488,145

Property and equipment, net	2,681	2,944
Operating lease right-of-use asset	7,501	7,961
Marketable securities, non-current	1,938	—
Other assets	21,181	20,961
Total assets	$ 460,130	$ 520,011
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 9,552	$ 12,250
Accrued expenses and other current liabilities	65,688	68,594
Deferred revenue	100,564	100,564
Amounts due to Pfizer	39,244	32,563
Cost share advance from Pfizer	8,555	33,818
Operating lease liability	2,256	2,148
Amounts due to related parties	382	393
Total current liabilities	226,241	250,330
Deferred revenue, non-current	350,565	375,706
Long-term operating lease liability	6,431	7,041
Long-term debt, less current maturities (related party)	358,700	358,700
Other liabilities	1,717	1,711
Total liabilities	943,654	993,488
Total shareholders' deficit	(483,524)	(473,477)
Total liabilities and shareholders' deficit	$ 460,130	$ 520,011

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