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

January 26, 2023

- *Third fiscal quarter 2022 total revenue of $100.2 million; including net product revenue of $61.4 million*
- *Net product revenue from U.S. sales of ORGOVYX® of $48.7 million in third fiscal quarter 2022, with sequential quarterly demand volume growth of 13% and cumulative patients estimated at 26,000 through December 2022*
- *Net product revenue from U.S. sales of MYFEMBREE® of $10.5 million in third fiscal quarter 2022, with sequential quarterly demand volume growth of 49% and cumulative patients estimated at 13,500 through December 2022*
- *Myovant remains well-capitalized with cash, cash equivalents, marketable securities, and amounts available under the Sumitomo Pharma Loan Agreement of $315.7 million as of December 31, 2022*
- *With respect to the previously announced merger of Myovant with Sumitovant Biopharma, the definitive proxy statement was filed with the SEC on January 23, 2023; the antitrust waiting period has expired and the special general meeting of shareholders to vote on the merger is set to take place on March 1, 2023*

BASEL, Switzerland, Jan. 26, 2023 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a biopharmaceutical company that aspires to redefine care for women and men through purpose-driven science, empowering medicines, and transformative advocacy, today announced financial results for the third quarter of fiscal year 2022 and provided other corporate updates.

"During the third quarter fiscal year 2022, our brands had outstanding performance and double-digit growth over the prior quarter, with ORGOVYX expanding leadership in the GnRH antagonist class for advanced prostate cancer and MYFEMBREE reaching more patients with uterine fibroids and endometriosis while continuing to grow the GnRH antagonist class for these indications," said David Marek, Chief Executive Officer of Myovant Sciences, Inc. Mr. Marek added, "We are also excited that our special general meeting of shareholders to vote on the merger with Sumitovant Biopharma is scheduled for March 1, 2023. If approved, we anticipate the closing of the merger to occur shortly thereafter."

Third Fiscal Quarter 2022 and Recent Corporate Updates

Merger Update

- On October 23, 2022, Myovant announced that it had entered into a merger agreement with Sumitovant Biopharma Ltd. (Sumitovant) and Sumitomo Pharma Co., Ltd. (Sumitomo Pharma) under which Sumitovant has agreed to acquire the remaining shares of Myovant that Sumitovant does not currently hold. Subject to the terms and conditions set forth in the merger agreement, in the event the merger is consummated, holders of Myovant common shares will be entitled to receive $27.00 per share in cash.
- The applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"), expired on January 2, 2023. The expiration of the waiting period under the HSR Act satisfies one of the conditions to consummation of the merger. Consummation of the merger remains subject to the satisfaction of certain other conditions.
- The definitive proxy statement was filed with the U.S. Securities and Exchange Commission (SEC) on January 23, 2023 and Myovant's special general meeting of shareholders to vote on the merger is set to take place on March 1, 2023.

ORGOVYX (relugolix 120 mg)

- Third fiscal quarter 2022 net product revenues for ORGOVYX in the U.S. were $48.7 million, reflecting 12% sequential growth compared to the second fiscal quarter 2022. ORGOVYX commercial demand volume grew 13% quarter-over-quarter driven by strong new patient starts and continued expansion across all treatment settings.
- Approximately 4,000 new patients started treatment with ORGOVYX in the third fiscal quarter of 2022, reaching approximately 26,000 cumulative patients since launch.
- ORGOVYX expanded its leadership in the gonadotropin-releasing hormone (GnRH) antagonist class for advanced prostate cancer with a 59% share based on months of therapy.
- Since launching in January 2021, ORGOVYX drove a 160% volume increase of the GnRH antagonist market for products approved by the U.S. Food and Drug Administration (FDA) for the treatment of advanced prostate cancer.

- In December 2022, Myovant completed a New Drug Submission to Health Canada seeking marketing approval for ORGOVYX for advanced prostate cancer.

- In October 2022, Myovant's commercialization partner, Accord Healthcare, Ltd. (Accord), launched ORGOVYX for the treatment of advanced hormone-sensitive prostate cancer in Europe. To date, Accord has launched ORGOVYX in Germany, Austria, Czech Republic, and the United Kingdom.

- On January 25, 2023, the first participant was enrolled in the Phase 3 REPLACE-CV study evaluating the risk of major cardiovascular events with ORGOVYX compared with leuprolide in patients with prostate cancer who require treatment with androgen deprivation therapy for at least one year.

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

- Third fiscal quarter 2022 net product revenues for MYFEMBREE in the U.S. were $10.5 million, reflecting 64% sequential growth compared to second fiscal quarter 2022. MYFEMBREE commercial demand volume grew 49% quarter-over-quarter driven by accelerating growth in new patient starts and prescribers.

- Approximately 4,500 new patients started treatment with MYFEMBREE in the third fiscal quarter 2022, resulting in approximately 13,500 cumulative patients and 50% sequential quarterly growth in the number of patients treated, since launch. MYFEMBREE reached 38% NBRx share (uterine fibroids and endometriosis) in December 2022 contributing to 29% TRx growth in the overall GnRH antagonist class since MYFEMBREE's launch.

- As of December 31, 2022, 75% commercial coverage has been obtained for MYFEMBREE's endometriosis indication, covering approximately 124 million lives in the U.S.

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

- In October 2022, the Type II variation application to the European Medicines Agency (EMA) filed by Myovant's commercialization partner, Gedeon Richter Plc. (Richter), seeking approval for RYEQO for the treatment of moderate to severe pain associated with endometriosis in adult women of reproductive age with a history of previous medical or surgical treatment for their endometriosis, was validated and accepted by the EMA. Pursuant to the Richter Development and Commercialization Agreement, the acceptance of the Type II variation application by the EMA triggered a $4.0 million milestone payment due from Richter, which Myovant received and recorded as Richter license and milestone revenue in the three months ended December 31, 2022.

Expected Upcoming Milestones

- Special general meeting of shareholders to vote on the merger with Sumitovant Biopharma is set to take place on March 1, 2023 and, if approved, the closing of the merger is expected to occur shortly thereafter.

- Myovant expects the FDA decision for the MYFEMBREE supplemental New Drug Application (sNDA) proposing updates to MYFEMBREE's U.S. Prescribing Information (USPI) based on the 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 for up to two years by the January 29, 2023 Prescription Drug User Fee Act (PDUFA) goal date.

- Myovant expects to submit an sNDA to the FDA for the SPIRIT 2-year long-term extension study for MYFEMBREE in women for the management of pain associated with endometriosis in the first half of calendar year 2023.

Third Fiscal Quarter 2022 Financial Summary

Total revenues for the three months ended December 31, 2022, and 2021 were $100.2 million and $54.4 million, respectively.

- **Product revenue, net** for the three months ended December 31, 2022, and 2021 was $61.4 million and $29.3 million, respectively. Product revenue, net consisted primarily of the following:

    - Product revenue, net from sales of ORGOVYX in the U.S. for the three months ended December 31, 2022 was $48.7 million compared to $24.4 million for the three months ended December 31, 2021.

    - Product revenue, net from sales of MYFEMBREE in the U.S. for the three months ended December 31, 2022 was $10.5 million compared to $2.4 million for the three months ended December 31, 2021.

- **Pfizer collaboration revenue** for the three months ended December 31, 2022, and 2021 was $29.3 million and $25.2 million, respectively. Pfizer collaboration revenue for both the three months ended December 31, 2022 and 2021 consists of the partial recognition of the upfront payment Myovant received from Pfizer in December 2020 and of the $100.0 million regulatory milestone payment Myovant received from Pfizer that was triggered upon the FDA approval of MYFEMBREE for

the management of heavy menstrual bleeding associated with uterine fibroids on May 26, 2021. Pfizer collaboration revenue for the three months ended December 31, 2022 also includes the partial recognition of the $100.0 million regulatory milestone payment Myovant received from Pfizer that was triggered upon the FDA approval of MYFEMBREE for the management of moderate to severe pain associated with endometriosis on August 5, 2022.

- **Accord license and milestone revenue** for the three months ended December 31, 2022 consists of the recognition of a $5.0 million milestone payment from Accord that was triggered upon Accord's first commercial sale of ORGOVYX in Europe in October 2022. There was no Accord license and milestone revenue for the three months ended December 31, 2021.

- **Richter license and milestone revenue** for the three months ended December 31, 2022 consists of the recognition of a $4.0 million regulatory milestone payment from Richter that was triggered upon the EMA acceptance of Richter's Type II variation submission for RYEQO for the treatment of moderate to severe pain associated with endometriosis in adult women of reproductive age with a history of previous medical or surgical treatment for their endometriosis. There was no Richter license and milestone revenue for the three months ended December 31, 2021.

Cost of product revenue for the three months ended December 31, 2022 was $7.4 million compared to $4.2 million for the three months ended December 31, 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 December 31, 2022 was due to an increase in cost of goods sold and royalty expense payable to Takeda primarily 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 December 31, 2022, was $26.8 million, compared to $12.1 million for the three months ended December 31, 2021, reflecting Pfizer's 50% share of net profits from sales of ORGOVYX and MYFEMBREE in the U.S. The increase in collaboration expense to Pfizer in the three months ended December 31, 2022 was primarily 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 December 31, 2022, and 2021 were $86.4 million and $72.1 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 due to higher headcount, and an increase in legal and professional fees related to activities associated with the merger agreement.

Research and development (R&D) expenses for the three months ended December 31, 2022, and 2021 were $31.5 million and $25.7 million, respectively. The increase in R&D expenses was primarily driven by higher personnel-related expenses, primarily due to higher headcount.

Interest expense for the three months ended December 31, 2022, and 2021 was $6.1 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 $3.2 million, as a result of an increase in interest rates as compared to the year ago period.

Income tax expense for the three months ended December 31, 2022, and 2021 was $1.2 million and $0.3 million, respectively. Myovant's tax expense currently relates principally to profits earned in the U.S.

Net loss for the three months ended December 31, 2022 was $57.6 million compared to $63.4 million for the year ago period. On a per common share basis, net loss was $0.59 and $0.68 for the three months ended December 31, 2022 and 2021, respectively.

Capital resources: Cash, cash equivalents, marketable securities, and amounts available under the Sumitomo Pharma Loan Agreement totaled $315.7 million in the aggregate as of December 31, 2022, and consisted of $274.4 million of cash, cash equivalents, and marketable securities and $41.3 million of available borrowing capacity under the Sumitomo Pharma Loan Agreement.

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 (EC) 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. The risk of major adverse cardiovascular events with ORGOVYX® compared with leuprolide is being assessed in adult men with prostate cancer requiring treatment with androgen deprivation therapy for at least one year.

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 GnRH treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, with a treatment duration of up to 24 months; and in August 2022 as the first and only once-daily oral GnRH antagonist combination treatment for the management of moderate to severe pain associated with endometriosis, with a treatment duration of 24 months. In July 2021 and August 2021, respectively, the EC and 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. 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 men through purpose-driven science, empowering medicines, and transformative advocacy worldwide. Founded in 2016, Myovant has executed multiple successful Phase 3 clinical trials across hormone-sensitive oncology and women's health

leading to five regulatory approvals in the United States and Europe. Myovant and its partners continue to file for additional indications of its lead products as well as continue further development of pipeline assets. 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.

About Sumitovant Biopharma Ltd.

Sumitovant is a technology-driven biopharmaceutical company accelerating development and commercialization of new potential therapies for patients with rare conditions and other diseases. Through its proprietary computing and data platforms, scientific expertise and diverse company portfolio, Sumitovant has supported development of multiple FDA-approved products and a robust pipeline of early- through late-stage investigational assets addressing unmet patient needs in pediatrics, urology, oncology, women's health, specialty respiratory and infectious diseases. Sumitovant, a wholly owned subsidiary of Sumitomo Pharma, is also the majority-shareholder of Myovant. Please visit Sumitovant's website at www.sumitovant.com for more information on Sumitovant and its portfolio.

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 about 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; statements regarding expectations about the proposed transaction involving Myovant and Sumitovant, including the timing of the special general meeting of shareholders and the timing of the closing of the merger; statements regarding the timing of Myovant's regulatory submissions, anticipated regulatory review results, as well as other statements under the caption "Expected Upcoming Milestones." In addition, risks and uncertainties related to the proposed transaction include, but are not limited to, the risk that the parties may be unable to achieve expected synergies and operating efficiencies in the merger within the expected timeframes or at all and to successfully integrate Myovant's operations into those of Sumitovant; such integration may be more difficult, time consuming or costly than expected; the risk that the proposed transaction does not close, due to the failure of one or more conditions to closing or otherwise; the risk that required Myovant shareholder approvals of the proposed transaction will not be obtained or that such approvals will be delayed or conditioned beyond current expectations; the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement; uncertainty as to the timing of completion of the proposed transaction; the risks related to the disruption of management time from ongoing business operations due to the proposed transaction and possible difficulties in maintaining customer, supplier, key personnel and other strategic relationships; and any litigation relating to the proposed transaction that has been or could be instituted against Myovant, Sumitovant or their respective directors or officers, including the effects of any outcomes related thereto; and the possibility of unexpected costs and liabilities related to the proposed transaction.

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 January 26, 2023, 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 December 31,		Nine Months Ended December 31,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	$ 61,422	$ 29,268	$ 152,720	$ 61,885
Pfizer collaboration revenue	29,307	25,172	109,025	79,853
Accord license and milestone revenue	5,000	—	55,000	—
Richter license and milestone revenue	4,000	—	4,300	31,667
Other revenue	500	—	500	—
Total revenues	100,229	54,440	321,545	173,405
Operating costs and expenses:				
Cost of product revenue (1)	7,418	4,243	17,275	7,897

Collaboration expense to Pfizer	26,808	12,086	67,242	25,912
Selling, general and administrative [1]	86,380	72,125	249,671	192,118
Research and development [1]	31,518	25,726	82,324	82,886
Total operating costs and expenses	152,124	114,180	416,512	308,813
Loss from operations	(51,895)	(59,740)	(94,967)	(135,408)
Interest expense	6,118	3,479	15,131	10,478
Interest income	(1,591)	(70)	(3,095)	(248)
Loss before income taxes	(56,422)	(63,149)	(107,003)	(145,638)
Income tax expense	1,205	296	17,482	1,058
Net loss and comprehensive loss	$ (57,627)	$ (63,445)	$ (124,485)	$ (146,696)
Net loss per common share — basic and diluted	$ (0.59)	$ (0.68)	$ (1.29)	$ (1.59)
Weighted average common shares outstanding — basic and diluted	96,859,108	93,474,985	96,155,644	92,514,657

[1] Includes the following share-based compensation:

Selling, general and administrative	$ 7,174	$ 4,173	$ 20,890	$ 18,131
Research and development	3,682	2,842	11,180	11,683
Cost of product revenue	120	32	329	50
Total share-based compensation	$ 10,976	$ 7,047	$ 32,399	$ 29,864

Revenue components are as follows:

Product revenue, net:				
ORGOVYX	$ 48,724	$ 24,393	$ 128,077	$ 53,535
MYFEMBREE	10,527	2,429	20,929	4,133
Accord product supply and royalties	387	—	387	—
Richter product supply and royalties	1,784	2,446	3,327	4,217
Total product revenue, net	61,422	29,268	152,720	61,885
Pfizer collaboration revenue:				
Amortization of upfront payment	20,974	20,974	62,922	62,922
Amortization of regulatory milestones	8,333	4,198	46,103	16,931
Total Pfizer collaboration revenue	29,307	25,172	109,025	79,853
Accord license and milestone revenue	5,000	—	55,000	—
Richter license and milestone revenue	4,000	—	4,300	31,667
Other revenue	500	—	500	—
Total revenues	$ 100,229	$ 54,440	$ 321,545	$ 173,405

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

	December 31, 2022	March 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 250,590	$ 406,704
Accounts receivable, net	41,021	23,296
Marketable securities	23,847	27,483
Inventories	30,084	7,584
Prepaid expenses and other current assets	38,047	22,498
Amount due from related party	2,997	580
Total current assets	386,586	488,145
Property and equipment, net	2,546	2,944
Operating lease right-of-use asset	7,098	7,961
Other assets	7,291	20,961
Total assets	$ 403,521	$ 520,011
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$ 12,217	$ 12,250
Accrued expenses and other current liabilities	87,333	68,594
Deferred revenue	117,231	100,564

Amounts due to Pfizer	25,768	32,563
Cost share advance from Pfizer	—	33,818
Operating lease liability	2,703	2,148
Amounts due to related parties	501	393
Total current liabilities	245,753	250,330
Deferred revenue, non-current	350,014	375,706
Long-term operating lease liability	5,480	7,041
Long-term debt, less current maturities (related party)	358,700	358,700
Other liabilities	1,717	1,711
Total liabilities	961,664	993,488
Total shareholders' deficit	(558,143)	(473,477)
Total liabilities and shareholders' deficit	$ 403,521	$ 520,011

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