Momenta Pharmaceuticals Reports First Quarter 2019 Financial and Operating Results

May 2, 2019

— M281 Phase 2 trials in MG and HDFN active and enrolling patients —

— Data supporting M281's mechanism in HDFN, as first anti-FcRn antibody to inhibit maternal-fetal IgG transfer in perfusion model of the human term placenta, published in American Journal of Obstetrics & Gynecology —

— First subjects dosed in Phase 1/2 M254 and IVIg crossover clinical trial in ITP —

CAMBRIDGE, Mass., May 02, 2019 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA), a biotechnology company focused on discovering and developing novel biologic therapeutics to treat rare immune-mediated diseases, today reported its financial results for the first quarter ended March 31, 2019.

"We continue to focus on operational execution to progress our ongoing trials of M281 and M254 towards key proof-of-concept data readouts in 2020," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "Additionally, we were proud to share new data on our pipeline this quarter with the publication of preclinical data highlighting both M281's potential to alter the treatment landscape in fetal-maternal disorders, and the ability of our SIFbody platform and Fc multimerization technology to produce enhanced antibodies across a range of immunomodulating targets."

First Quarter 2019 Highlights, Recent Events and Anticipated Upcoming Milestones

Novel Therapeutics Pipeline:

M281 (anti-FcRn): a fully human anti-neonatal Fc receptor (FcRn) aglycosylated immunoglobulin G (IgG1) monoclonal antibody (mAb)

- Vivacity-MG, the Company's Phase 2 study of M281 in generalized Myasthenia Gravis (gMG), is expected to report top-line results in 2020. Unity, the Company's global multi-center Phase 2 clinical study of M281 in Hemolytic Disease of the Fetus and Newborn (HDFN), is expected to report top-line results in 2021. This follows the March 2019 announcement that regulatory approvals were obtained in the U.S., Canada and several EU countries and that the Company began activating clinical sites.

- In March 2019, the Company published data in the American Journal of Obstetrics & Gynecology, expanding on its February 2019 presentation at the Society for Maternal-Fetal Medicine 39th Annual Pregnancy Meeting, which highlighted the ability of M281 to inhibit transfer of immunoglobulin G from maternal to fetal circulation in an *ex vivo* placental perfusion model with minimal transfer of M281 into fetal circulation.

- The Company plans to initiate a third study of M281 in an additional autoimmune indication in 2019.

M254 (hsIgG): a hypersialylated immunoglobulin designed as a high potency alternative for intravenous immunoglobulin (IVIg)

- In January 2019, the Company announced that the first subject was dosed in the Phase 1/2 clinical trial in idiopathic thrombocytopenic purpura (ITP). The multi-part trial is first enrolling healthy volunteers and includes single and multiple dose studies, and a randomized cross-over study comparing M254 to IVIg. Enrollment for this trial is ongoing and preliminary clinical data is expected in 2020.

M230 (CSL730): a recombinant Fc multimer being developed in collaboration with CSL

- The Phase 1 clinical trial in healthy volunteers to evaluate the safety and tolerability of M230 continues. Momenta's partner, CSL expects to complete the Phase 1 study by the end of 2019.

SIFbody Platform and Fc Multimerization Technology:

- The Company presented two posters at the American Association for Cancer Research (AACR) Annual Meeting in April 2019, demonstrating the potential of its SIFbody platform and Fc multimerization technology to significantly enhance the potency and efficacy of a variety of cell depleting therapeutic antibodies, including antibodies targeting CD38 and CTLA-4.

Legacy Products:

Glatopa® 20 mg and 40 mg: FDA approved generic versions of COPAXONE 20 mg and 40 mg, developed and commercialized in collaboration with Sandoz

- In the first quarter of 2019, Momenta recorded $2.4 million in product revenue from Sandoz's sales of Glatopa products.

M923: a fully-owned proposed biosimilar to HUMIRA® (adalimumab)

- In November 2018, the Company announced license agreements with AbbVie, providing worldwide rights for the launch of M923. Under the terms of the agreements, and subject to approval by health regulatory authorities, Momenta may launch M923 worldwide based on agreed-to launch dates, including in the U.S. in November 2023. Momenta is currently seeking a commercialization partner for this product.

M710: a proposed biosimilar to EYLEA® (aflibercept) candidate being developed in collaboration with Mylan

- Mylan continues its pivotal clinical trial in patients with diabetic macular edema to compare safety, efficacy and immunogenicity of M710 with EYLEA.

- In January 2019, Momenta's formal notice of termination for all other biosimilar candidates previously subject to the collaboration agreement with Mylan became effective.

First Quarter 2019 Financial Results

Revenue: In the first quarter of 2019, the Company recorded $2.4 million in product revenue from Sandoz's sales of Glatopa, net of a deduction of $1.5 million for legal settlement and royalty payments to Teva Pharmaceutical Industries. In the first quarter of 2018, the Company recorded $3.5 million in product revenue, net a deduction of $9.8 million for 50% of Glatopa 40 mg/mL inventory reserved by Sandoz. The decrease in product revenue from the prior year period was primarily due to continued competition.

Research and development revenue for the first quarter of 2019 was $1.8 million, compared to $1.3 million in the same quarter in 2018. The increase in research and development revenue of $0.5 million, or 38%, was primarily due to higher revenue recognized on the collaborative upfront payment from Mylan of $0.6 million, offset in part by lower reimbursement revenue for Glatopa expenses of $0.2 million.

Total revenue for the first quarter of 2019 was $4.1 million compared to $4.9 million for the same period in 2018.

Operating Expenses: Total GAAP operating expenses were $52.2 million in the first quarter of 2019.

Research and development expenses for the first quarter of 2019 were $28.0 million, compared to $33.2 million for the same period in 2018. The decrease of $5.2 million, or 16%, was primarily due to cost savings following our workforce reduction in the fourth quarter of 2018 and lower lease costs, offset by increased costs related to our M281 clinical trials.

General and administrative expenses for the first quarter of 2019 were $24.2 million, compared to $20.6 million for the same period in 2018. The increase of $3.6 million, or 17%, was primarily driven by depreciation and legal costs, offset by savings in costs following our workforce reduction in the fourth quarter of 2018.

First quarter 2019 non-GAAP operating expense was $48.3 million. Non-GAAP operating expense is total operating expenses, less stock-based compensation expense, restructuring expense and collaborative reimbursement revenue. See "Non-GAAP Financial Information and Other Disclosures" and the table below entitled "Reconciliation of GAAP Results to Non-GAAP Financial Measures" for a reconciliation of GAAP operating expense to non-GAAP operating expense.

Net Income (Loss): The Company reported a net loss of $44.8 million, or $0.46 per share for the first quarter of 2019 compared to a net loss of $47.6 million, or $0.63 per share, for the same period in 2018.

Cash Position: At March 31, 2019, Momenta had $416.5 million in cash, cash equivalents and marketable securities compared to $449.4 million at December 31, 2018.

2019 Financial Guidance

Momenta provides non-GAAP operating expense guidance, which it believes can enhance an overall understanding of its financial performance when considered together with GAAP financial measures. Refer to the section of this press release below entitled "Non-GAAP Financial Information and Other Disclosures" for further discussion of this subject.

Non-GAAP operating expense is total operating, less stock-based compensation expense, restructuring expense and collaborative reimbursement revenue. Momenta re-affirms its quarterly non-GAAP operating expense guidance of $45 - $55 million for 2019.

Non-GAAP Financial Information and Other Disclosures

Momenta uses a non-GAAP financial measure, non-GAAP operating expense, to provide operating expense guidance. Momenta believes this non-GAAP financial measure is useful to investors because it provides greater transparency regarding Momenta's operating performance as it excludes non-cash stock compensation expense, restructuring expense and collaborative reimbursement revenue. This non-GAAP financial measure should not be considered a substitute or an alternative to GAAP total operating expense and should not be considered a measure of Momenta's liquidity. Instead, non-GAAP operating expense should only be used to supplement an understanding of Momenta's operating results as reported under GAAP. Momenta has not provided GAAP reconciliation for its forward-looking non-GAAP annual or quarterly operating expense because Momenta cannot reliably predict without unreasonable efforts the timing or amount of the factors that substantially contribute to the projection of stock

compensation expense, which is excluded from the forward-looking non-GAAP financial measure. The Company has provided the estimated reconciling information that is available without unreasonable effort in the section of this press release above entitled “2019 Financial Guidance.”

Conference Call Information

Management will host a conference call and webcast today at 8:30 am ET to discuss these results and provide an update on the Company. A live webcast of the conference call may be accessed on the “Investors” section of the Company’s website, www.momentapharma.com. Please go to the site at least 15 minutes prior to the call to register, download, and install any necessary software. An archived version of the webcast will be posted on the Momenta website approximately two hours after the call.

To access the call, you may also dial (877) 224-9084 (domestic) or (720) 545-0022 (international) prior to the scheduled conference call time and provide the access code 8949569. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through 8949569. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 7484068.

About Momenta

Momenta Pharmaceuticals is a biotechnology company with a validated innovative scientific platform focused on discovering and developing novel therapeutics to treat rare, immune-mediated diseases and advancing its late stage biosimilar portfolio. The company is headquartered in Cambridge, MA.

To receive additional information about Momenta, please visit the website at www.momentapharma.com, which does not form a part of this press release.

Forward Looking Statements

Statements in this press release regarding management’s future expectations, beliefs, intentions, goals, strategies, plans or prospects, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements about the timing of our regulatory filings for clinical development and marketing approval; the timing of regulatory approval and launch of our product candidates; development timelines; the Company’s ability to meet its development and strategic goals; market potential and revenue of our products and product candidates, design, timing and goals of clinical trials and the availability, timing and announcement of data and results; the use, efficacy, safety, potency, tolerability, convenience and commercial potential of our product candidates, including their potential as best-in-class agents; future legal proceedings; expectations regarding accounting treatment for and recognition of consideration and revenue under the Company’s collaborations; reconciling information; non-GAAP operating expense guidance; and anticipated collaborative reimbursement revenue. Forward-looking statements may be identified by words and phrases such as “advance,” “anticipate,” ‘being developed,” “believe,” “continue,” “expect,” “guidance,” “look forward to,” “may,” “plan,” “possible,” “potential,” “progress,” “propose,” “remains,” “target,” “will,” “working toward” and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including those referred to under the section “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. As a result of such risks, uncertainties and factors, the Company’s actual results may differ materially from any future results, performance or achievements discussed in or implied by the forward-looking statements contained herein. The Company is providing the information in this press release as of this date and assumes no obligations to update the information included in this press release or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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MOMENTA PHARMACEUTICALS, INC.

Unaudited Condensed Consolidated Balance Sheets

(in thousands)

	March 31, 2019	December 31, 2018
Assets		
Cash, cash equivalents and marketable securities	$ 416,453	$ 449,411
Collaboration receivable	2,986	11,371
Restricted cash	37,898	37,898
Other assets	101,113	32,883
Total assets	$ 558,450	$ 531,563

Liabilities and Stockholders' Equity		
Current liabilities	$ 51,580	$ 51,511
Deferred revenue, net of current portion	743	1,774
Other long-term liabilities	83,569	17,270
Stockholder's equity	422,558	461,008
Total liabilities and stockholders' equity	$ 558,450	$ 531,563

MOMENTA PHARMACEUTICALS, INC.

Unaudited Condensed Statements of Operations and Comprehensive Loss

(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2019	**2018**
Collaboration revenues:		
Product revenue	$ 2,352	$ 3,521
Research and development revenue	1,761	1,331
Total collaboration revenue	4,113	4,852
Operating expenses:		
Research and development	27,972	33,242
General and administrative	24,206	20,612
Restructuring	26	—
Total operating expenses	52,204	53,854
Loss from operations	(48,091)	(49,002)
Other income, net	3,248	1,371
Net loss	$ (44,843)	$ (47,631)
Net loss per share:		
Basic and diluted	$ (0.46)	$ (0.63)
Shares used in calculating net loss per share		
Basic and diluted	98,195	75,454
Comprehensive loss	$ (44,501)	$ (48,066)

MOMENTA PHARMACEUTICALS, INC.

Reconciliation of GAAP Results to Non-GAAP Financial Measures

(In thousands)

(unaudited)

A reconciliation of historical GAAP operating expenses to Non-GAAP operating expenses is as follows:

	Three Months Ended March 31,	
	2019	**2018**
GAAP operating expenses	$ 52,204	$ 53,854
Adjustments:		
Restructuring	(26)	—
Non-cash stock compensation expense	(3,474)	(4,874)
Collaboration expenses that are recorded as revenue and are reimbursable by collaborators	(420)	(583)

Non-GAAP operating expenses	$ 48,284	$ 48,397

Source: Momenta Pharmaceuticals, Inc.