November 1, 2017

Momenta Pharmaceuticals Reports Third Quarter 2017 Financial Results and Provides Corporate Update

-- Ended third quarter with a strong cash position of $423M --

CAMBRIDGE, Mass., Nov. 01, 2017 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today reported its financial results for the third quarter ended September 30, 2017 and provided a corporate update.

"We continue to believe in the potential for the approval and launch of Glatopa® 40 mg in late 2017 or early 2018 and that there remains a meaningful market opportunity for this product in the U.S.," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "In the third quarter of 2017, we continued to advance our broad portfolio of biosimilar and novel drug candidates and more recently we were thrilled to announce the promotion of our co-founder, Ganesh Kaundinya, to Chief Operating Officer. We look forward to his continued contributions as we progress our robust portfolio of drug candidates."

Third Quarter Highlights and Recent Events

Complex Generics:

Glatopa® 20 mg: First FDA-approved, substitutable generic daily COPAXONE® 20 mg (glatiramer acetate injection) for patients with relapsing forms of multiple sclerosis developed in collaboration with Sandoz

- In the third quarter of 2017, Momenta recorded $10.9 million in product revenues from Sandoz's Glatopa 20 mg sales.
- In the third quarter of 2017, Momenta earned a $10 million milestone payment from Sandoz in connection with Glatopa 20 mg's status at that time as the sole FDA-approved generic of COPAXONE 20 mg in the U.S. two years following its launch.

Glatopa 40 mg: Designed to be a generic version of three-times-a-week COPAXONE 40 mg for patients with relapsing forms of multiple sclerosis developed in collaboration with Sandoz

- The Abbreviated New Drug Application (ANDA) submitted by Sandoz is under U.S. Food and Drug Administration (FDA) review. An approval of the application is dependent on the satisfactory resolution of the compliance observations stated in the FDA warning letter issued in February 2017 to Pfizer, the contracted fill/finish manufacturing partner for Glatopa. Pfizer has submitted a comprehensive response to the observations cited in the warning letter. The Company believes that marketing approval from the FDA continues to be possible in late 2017 or early 2018.

Biosimilars:

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

- Momenta is working toward the first submission for marketing approval of M923 in late 2017. The Company expects first U.S. market formation for biosimilar versions of HUMIRA to begin in the 2022 - 2023 timeframe subject to marketing approval, patent considerations and litigation timelines.

M834: a proposed biosimilar to ORENCIA (abatacept) being developed in collaboration with Mylan

- Momenta today announced that M834 did not meet its primary pharmacokinetic endpoints in a Phase 1 study to compare the pharmacokinetics, safety and immunogenicity of M834 to US- and EU-sourced ORENCIA in normal healthy volunteers. Momenta and Mylan continue to gather and analyze these data to inform the next steps for the program.

M710: a biosimilar candidate being developed in collaboration with Mylan

- Momenta and Mylan continue to progress M710 and are targeting a first regulatory submission for clinical development by early 2018.

Novel Drugs for Autoimmune Indications:

M281 (anti-FcRn): a fully human monoclonal antibody (mAb) targeting the neonatal Fc receptor (FcRn)

- In August 2017, the Company completed the multiple ascending dose portion of the Phase 1 study in healthy volunteers. The Company plans to report the top-line data from the multiple ascending dose portion of the study in the fourth quarter of 2017.

M230 (SIF3): a Selective Immunomodulator of Fc receptors being developed in collaboration with CSL

- In September 2017, Momenta announced that it opted into a 50% cost and profit sharing arrangement for all products developed under the CSL agreement, including M230. Under the agreement Momenta will fund 50% of global research and development and U.S. commercialization and manufacturing costs in exchange for 50% of U.S. profits. Royalties remain payable to Momenta for territories outside the U.S. and milestones are reduced.
- Momenta and CSL have agreed upon a development plan for M230 and CSL is targeting a clinical trial in late 2017, subject to regulatory feedback.

M254 (hsIVIg): a robust, controlled sialylation process to generate tetra-Fc-sialylated immunoglobulins with consistent enhanced anti-inflammatory activity

- The Company continues to progress the M254 program and expects to initiate an IND-enabling toxicology study in 2017 and is targeting a clinical trial in 2018.

Third Quarter 2017 Financial Results

Revenue: In the third quarter of 2017, the Company recorded $10.9 million in product revenues from Sandoz's sales of Glatopa 20 mg compared to $23.3 million for the same period in 2016. The decrease in product revenues of $12.4 million, or 53%, was primarily due to higher sales deductions for Medicaid rebates, inventory price adjustments relating to Mylan's entry into the COPAXONE market and a deduction of $0.2 million for reimbursement to Sandoz of the Company's share of Glatopa-related legal expenses in the third quarter of 2017. In addition, under the terms of the collaboration agreement with Sandoz, the $10 million commercial milestone payment Momenta earned from Sandoz in the third quarter of 2017 was deducted from net profit prior to the calculation of Momenta's 50% profit share.

Research and development revenue for the third quarter of 2017 was $13.2 million compared to $5.8 million recorded in the same quarter last year. The increase in research and development revenue of $7.4 million, or 128%, was primarily due to a $10 million commercial milestone payment earned by the Company on July 1, 2017 in connection with GLATOPA 20 mg/mL's continuing to be the sole FDA-approved generic of COPAXONE at that time and achieving a certain level of contractually defined profits in the United States, partially offset by less revenue due to the termination of the Baxalta Collaboration Agreement, effective December 31, 2016, under which the Company was reimbursed for M923 employee expenses and external costs and for which Momenta recognized a portion of Baxalta's initial upfront payment in the third quarter of 2016.

Total revenues for the third quarter of 2017 were $24.1 million compared to $29.1 million for the same period in 2016.

Operating Expenses: Total GAAP operating expenses were $58.6 million in the third quarter of 2017. Research and development expenses for the third quarter of 2017 were $37.9 million, compared to $31.6 million for the same period in 2016. The increase of $6.3 million, or 20%, was primarily due to $12.4 million in increased spending on M923, as the program was transitioned back to Momenta effective December 31, 2016 in connection with the termination of the Baxalta Collaboration Agreement, partially offset by a $3.4 million reduction in spend on the necuparanib program, which was discontinued in August 2016, and a $2.6 million lower spend on M230 as those costs are now shared with CSL.

General and administrative expenses for the third quarter of 2017 were $20.7 million, compared with $15.8 million for the same period in 2016. The increase of $4.9 million, or 31%, was primarily driven by approximately $3.3 million in legal fees relating to ongoing litigation and $0.8 million in personnel-related expenses driven by increased headcount and higher share-based compensation expense.

Third quarter non-GAAP operating expense was $51.6 million, at the lower end of previously provided guidance of $50 -

$60 million for the fourth quarter of 2017. 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 Loss: The Company reported a net loss of $33.2 million, or $0.44 per share for the third quarter of 2017 compared to a net loss of $17.5 million, or $0.26 per share for the same period in 2016.

Cash Position: At September 30, 2017, Momenta had $423.1 million in cash, cash equivalents and marketable securities compared to $456.8 million at June 30, 2017.

2017 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 expenses (which excludes collaboration expenses reimbursable by Mylan), less stock-based compensation expense and collaborative reimbursement revenues. Today, Momenta is providing updated non-GAAP operating expense guidance of approximately $200 - $210 million for 2017 and $43 - $53 million for the fourth quarter of 2017. The annual guidance includes approximately $50 million of spending on M923 that, as a result of Shire's termination of the Baxalta collaboration agreement, will now be included in the Company's 2017 operating expenses. The $50 million spend has been fully paid by Shire as part of the termination agreement.

The Company expects to recognize the $50 million upfront payment from CSL as revenue in the fourth quarter of 2017 and continues to expect to recognize revenue from Mylan's $45 million upfront payment on a quarterly basis. The Company also estimates that collaborative reimbursement revenues will be approximately $0 - $2 million in the fourth quarter of 2017.

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 and collaborative reimbursement revenues. 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 "2017 Financial Guidance."

Conference Call Information

Management will host a conference call and webcast today at 10:00 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 in order 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 6492819. A replay of the call will be available approximately two hours after the conclusion of the call and will be accessible through November 8, 2017. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code 6492819.

About Momenta

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex drugs and is headquartered in Cambridge, MA. Momenta is applying its technology to the development of generic versions of complex drugs, biosimilar and potentially interchangeable biologics, and to the discovery and development of novel therapeutics for autoimmune indications.

To receive additional information about Momenta, please visit the website at www.momentapharma.com, which does not

form a part of this press release.

Our logo, trademarks, and service marks are the property of Momenta Pharmaceuticals, Inc. All other trade names, trademarks, or service marks are property of their respective owners.

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, including Glatopa 40 mg; development timelines; the Company's ability to meet its development and strategic goals; market potential and product revenues of our products and product candidates; the contribution of our Chief Operating Officer; timing of biosimilar market formation; the next steps for M834; timing of clinical trials and the timing, availability and announcement of data and results; the CSL cost and profit sharing arrangement; expectations regarding accounting treatment for and recognition of consideration and revenues under the Company's collaborations; reconciling information; non-GAAP operating expense guidance; anticipated collaborative reimbursement revenues and anticipated spend on M923 and its inclusion in operating expenses. 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, 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)

	September 30, 2017	December 31, 2016
Assets		
Cash, cash equivalents and marketable securities	$ 423,078	$ 353,151
Collaboration receivable	14,333	70,242
Other assets	65,131	54,344
Total assets	$ 502,542	$ 477,737
Liabilities and Stockholders' Equity		
Current liabilities	$ 106,259	$ 70,676
Deferred revenue, net of current portion	29,845	31,360
Other long-term liabilities	5,924	3,793
Stockholder's equity	360,514	371,908
Total liabilities and stockholders' equity	$ 502,542	$ 477,737

MOMENTA PHARMACEUTICALS, INC.
Unaudited Condensed Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)

	Three Months Ended	Nine Months Ended

	September 30,		September 30,	
	2017	2016	2017	2016
Collaboration revenues:				
Product revenue	$ 10,890	$ 23,339	$ 53,434	$ 58,831
Research and development revenue	13,200	5,805	20,840	16,593
Total collaboration revenue	24,090	29,144	74,274	75,424
Operating expenses:				
Research and development	37,914	31,568	113,078	93,498
General and administrative	20,703	15,758	66,380	46,301
Total operating expenses	58,617	47,326	179,458	139,799
Operating loss	(34,527)	(18,182)	(105,184)	(64,375)
Other income, net	1,339	638	3,329	1,833
Net loss	$ (33,188)	$ (17,544)	$ (101,855)	$ (62,542)
Net loss per share basic and diluted	$ (0.44)	$ (0.26)	$ (1.40)	$ (0.91)
Weighted average number of common shares used in net loss per share basic and diluted	74,611	68,799	72,585	68,540

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
GAAP operating expenses	$ 58,617	$ 47,326	$ 179,458	$ 139,799
Adjustments:				
Non-cash stock compensation expense	(4,916)	(4,939)	(16,309)	(14,756)
Collaboration expenses that are reimbursable by collaborators	(2,078)	(1,522)	(6,541)	(4,661)
Non-GAAP operating expenses	$ 51,623	$ 40,865	$ 156,608	$ 120,382

Source: Momenta Pharmaceuticals, Inc.