



January 6, 2017

## Momenta Provides Year-End 2016 Corporate Update

-- New collaboration and license agreement with CSL to develop Fc multimer programs, including M230, with a \$50M upfront license fee --

-- Agreement with Shire to receive full rights to M923 and a \$51M one-time return payment --

CAMBRIDGE, Mass., Jan. 06, 2017 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today provided a corporate update and reviewed key anticipated highlights for 2017.

"This week we announced a significant research collaboration and license agreement with CSL for M230 and potential future Fc multimer programs. We also announced an agreement with Shire for the early return of full rights to the M923 program," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "We start 2017 with a strong balance sheet, a validation of our approach to Fc biology, a fully-owned biosimilar HUMIRA candidate that remains on track for regulatory submission in mid-2017, and the potential for the approval and launch by Sandoz of Glatopa<sup>®</sup> 40 mg product in the first quarter of 2017."

### Recent and Year-End 2016 Updates and 2017 Anticipated Milestones

#### BIOSIMILARS

**M923:** a fully-owned proposed biosimilar of HUMIRA<sup>®</sup> (adalimumab)

- | On January 3, 2017 the Company announced it will receive a one-time asset return payment of \$51.2 million from Shire for the early termination of the collaboration agreement to develop and commercialize M923. The collaboration termination was first announced in September 2016. Momenta will use the one-time payment to fund the estimated costs that would have been incurred by Shire through September 2017.
- | In November 2016, the Company announced positive Phase 3 top-line results of M923 in patients with moderate-to-severe chronic plaque psoriasis.
- | Momenta is targeting mid-2017 for the first submission for marketing approval of M923.

**M834:** a proposed biosimilar of ORENCIA<sup>®</sup> (abatacept) being developed in collaboration with Mylan

- | Momenta and Mylan initiated a Phase 1 trial in November 2016 and patient accrual is currently ongoing. The companies plan to report top-line data from the Phase 1 trial in the second half of 2017.
- | In November, Momenta received a milestone payment of \$25.0 million from Mylan to be applied toward the funding of Mylan's 50% share of collaboration expenses.
- | On December 22, 2016, the U.S. Patent and Trademark Office's Patent Trial and Appeal Board issued their decision upholding the validity of U.S. Patent No. 8,476,239, related to Bristol Myers Squibb's ORENCIA (abatacept) product following the Company's Inter Partes Review challenging this patent. The Company is considering its options for appeal to the U.S. Court of Appeals for the Federal Circuit.

**M710:** an early-stage biosimilar candidate being developed in collaboration with Mylan

- | In December, Momenta received a \$35.0 million milestone payment from Mylan to be applied toward the funding of Mylan's 50% share of collaboration expenses.

#### COMPLEX GENERICS

**Glatopa:** First FDA-approved, substitutable generic daily COPAXONE<sup>®</sup> 20 mg for multiple sclerosis

- | Glatopa 20 mg remains the sole generic 20 mg product on the market with approximately 40% penetration of the once-daily 20 mg/mL U.S. glatiramer acetate market.
- | Momenta expects that in the fourth quarter of 2016 its share of profit on Sandoz's sales of Glatopa 20 mg will be reduced by approximately \$3.5 million to reimburse Sandoz for the Company's share of Glatopa-related legal expenses.
- | The Abbreviated New Drug Application (ANDA) submitted by Sandoz for a three-times-a-week generic COPAXONE<sup>®</sup> 40 mg (glatiramer acetate injection) is under U.S. Food and Drug Administration (FDA) review. A tentative approval, if any, for Glatopa 40 mg could be granted at any time and a final approval could be granted following the expiration of COPAXONE 40 mg regulatory exclusivity on January 28, 2017.
- | A district court trial challenging four of Teva's five Orange Book-listed patents for COPAXONE 40 mg (glatiramer acetate injection) concluded on October 6, 2016. The Company expects a decision to be issued in the first quarter of 2017.

## NOVEL DRUG CANDIDATES

### **M230 (SIF3):** a Selective Immunomodulator of Fc receptors

- | On January 5, 2017, the Company announced that it has entered into a worldwide license agreement and an exclusive research collaboration with CSL to develop and commercialize Fc multimer proteins, including Momenta's M230, a selective immunomodulator of Fc receptors, expected to enter the clinic in 2017. The effectiveness of agreement is subject to clearance under the Hart-Scott-Rodino Act.
- | When the agreement becomes effective, Momenta will receive a \$50 million upfront license fee from CSL and is eligible to receive up to \$550 million in future milestone and royalty payments for M230. In addition to advancing M230, the agreement initiates a research collaboration to develop additional Fc multimer proteins that may originate from Momenta's or CSL's research.

### **M281:** Fully human monoclonal antibody (mAb) targeting the neonatal Fc receptor (FcRn), currently in an ongoing Phase 1 study

- | The Company has successfully completed five cohorts in the Phase 1 single ascending dose (SAD) study in healthy volunteers. In the SAD portion of the study a single dose of 30 mg/kg achieved up to 80% reduction of circulating IgG antibodies. M281 was well-tolerated and no serious adverse events were observed.
- | The Company plans to report the full data from the single and multiple ascending dose portions of the study in the second half of 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 figures. Refer to the section of this press release below entitled "Non-GAAP Financial Information and Other Disclosures" for further discussion of this subject.

- | Today, Momenta reiterated its non-GAAP operating expense guidance of approximately \$40 - \$45 million for the fourth quarter of 2016. Non-GAAP operating expense is total operating expenses (which is net of Mylan's share of collaboration expenses), excluding stock-based compensation expense and net of collaborative reimbursement revenues from Sandoz and Baxalta, now part of Shire.
- | The Company expects to report approximately \$350.0 million of cash, cash equivalents and marketable securities at December 31, 2016. This cash balance does not include the expected one-time payment of \$51.2 million from Shire nor the expected \$50.0 million upfront payment from CSL.
- | The Company is currently assessing the U.S. GAAP accounting treatment for the Shire and CSL agreements and plans to discuss the accounting for these transactions, as well as provide 2017 financial guidance on its fourth quarter and full year earnings conference call and webcast to be held on February 21, 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 and excludes non-cash stock compensation expense and is net of collaborative reimbursement revenues from Sandoz and Baxalta. This non-GAAP financial measure should not be considered an alternative to GAAP total operating expense and should not be considered a measure of Momenta's liquidity. Non-GAAP financial measures should not be considered as substitutes for measures calculated in accordance with GAAP and should only be used to supplement an understanding of Momenta's operating results as reported under GAAP. Momenta has not provided a GAAP reconciliation for its forward-looking non-GAAP fourth quarter 2016 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 anticipated reconciling information that is available without unreasonable effort in the section of this press release above entitled "Financial Guidance."

## **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](http://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 Company's ability to meet its development goals; expectations regarding long-term growth and sustainability; program costs, operating expenses, profits and cash and cash equivalents for the fourth quarter of 2016 and at December 31, 2016; the effectiveness, future payments and number of products to be developed under the CSL agreement; program development and collaboration plans; timing of regulatory submissions, regulatory approvals and product launches; timing of clinical trials and the availability and announcement of clinical data; timing of patent litigation and other patent-related proceedings and decisions and available options related to such litigation and proceedings; and the ability to generate value from our product candidates. Forward-looking statements may be identified by words such as "believe," "continue," "expect," "guidance," "opportunity," "plan," "possible," "potential," "will" 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 September 30, 2016, 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 preliminary, unaudited financial information provided above is based on the Company's current estimate of its non-GAAP operating expense for the fourth quarter of 2016, and its cash, cash equivalents and marketable securities at December 31, 2016, and remains subject to change based on the Company's closing procedures, including execution of its internal controls over financial reporting, and the subsequent occurrence or identification of events prior to the formal issuance of the Company's annual audited financial statements. 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.

### INVESTOR CONTACT:

Sarah Carmody

Momenta Pharmaceuticals

1-617-395-5189

[IR@momentapharma.com](mailto:IR@momentapharma.com)

### MEDIA CONTACT:

Karen Sharma

MacDougall Biomedical Communications

1-781-235-3060

[Momenta@macbiocom.com](mailto:Momenta@macbiocom.com)

 Primary Logo

Source: Momenta Pharmaceuticals, Inc.

News Provided by Acquire Media