November 29, 2016

Momenta Pharmaceuticals Announces Positive Top-Line Phase 3 Results for M923, a Proposed HUMIRA® (adalimumab) Biosimilar

CAMBRIDGE, Mass., Nov. 29, 2016 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today announced that the confirmatory Phase 3 clinical study of M923, a biosimilar HUMIRA® (adalimumab) candidate developed in collaboration with Baxalta, now part of Shire plc, in patients with moderate-to-severe chronic plaque psoriasis, met its primary endpoint. The proportion of subjects in the study who achieved the primary endpoint, at least 75% reduction in the Psoriasis Area and Severity Index (PASI-75) following 16 weeks of treatment, was equivalent between M923 and HUMIRA. The estimated difference in responders was well within the pre-specified confidence interval, confirming equivalence.

Equivalence was also achieved in all secondary efficacy endpoints, including the achievement of PASI-50, PASI-90, proportion achieving clear or near-clear skin, and change from baseline in absolute PASI score. Adverse events were comparable in terms of type, frequency, and severity, and were consistent with the published safety data for HUMIRA.

"These positive data support the biosimilarity of M923, and further advance us toward our goal of gaining regulatory approval for this important program," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "These data also validate the strength of our technology and show our commitment to expanding treatment access and providing additional options for patients who suffer from chronic inflammatory diseases."

This was a confirmatory, randomized, double-blind, multicenter study evaluating the efficacy, safety and immunogenicity of M923 in adult patients with moderate-to-severe chronic plaque psoriasis. Patients received up to 48 weeks of treatment with M923, HUMIRA, or HUMIRA alternating with M923. The full dataset from this study will be presented at future conferences and in future publications.

In 2011, Momenta Pharmaceuticals and Baxter Bioscience (subsequently Baxalta), now part of Shire, entered into the collaboration to develop and commercialize M923. Earlier this year, Shire announced it had made a strategic decision to end its biosimilars program and is now in the process of transitioning M923 to Momenta Pharmaceuticals, enabling Shire to further pursue its focus on serving people with rare diseases and other highly specialized conditions.

About M923, a proposed biosimilar of HUMIRA® (adalimumab)

M923 is being developed as a biosimilar candidate for HUMIRA, an anti-TNF monoclonal antibody. HUMIRA, the largest selling therapeutic on the market today, is a significant intervention for patients with autoimmune/inflammatory diseases. Adalimumab is used to treat many such conditions including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa and uveitis.

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.

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 development goals and regulatory approval goals for M923; commercial availability and effectiveness of M923; and the expectations about the analysis, clinical significance and future presentation of the full dataset from the Phase 3 study. Forward-looking statements may be identified by words such as "continue," "expect," "guidance," "look forward," "opportunity," "plan," "potential," "schedule," "target," "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 the Company's ability to fund the M923 program and obtain necessary regulatory approvals and the outcome of related patent litigation and patent-related proceedings, as well as those factors set forth in 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 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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Source: Momenta Pharmaceuticals, Inc.