



Momenta Pharmaceuticals Announces FDA Approval and Launch of Glatopa® (glatiramer acetate injection) 40 mg/mL

February 13, 2018

--Glatopa 40 mg/mL is a fully substitutable, AP-rated generic version of three times-a-week COPAXONE® (glatiramer acetate injection) 40 mg/mL for the treatment of patients with relapsing forms of multiple sclerosis (MS)--

--Glatopa 40 mg/mL joins the Sandoz glatiramer acetate injection portfolio along with Glatopa 20 mg/mL, which was launched in the US in June 2015--

CAMBRIDGE, Mass., Feb. 13, 2018 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today announced that the U.S. Food and Drug Administration (FDA) has approved Sandoz's Abbreviated New Drug Application for Glatopa (glatiramer acetate injection) 40 mg/mL and that Sandoz has initiated the launch of this product in the US. Glatopa was developed under a collaboration agreement between Momenta and Sandoz and is produced in the US.

Glatopa 40 mg/mL is FDA-approved as a fully substitutable, AP-rated generic version of three times-a-week COPAXONE 40 mg/mL therapy for patients with relapsing forms of multiple sclerosis (MS). In April 2015, the collaboration's Glatopa 20 mg/mL product received FDA approval and remained the only generic glatiramer acetate product on the market for over two years.

"This approval further validates the strength of our physicochemical and biological characterization capabilities," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "We are very proud to once again be able to provide patients with relapsing-forms of MS with a cost effective, high-quality generic alternative treatment option."

Momenta will provide a corporate update, including an update on the approval and launch of Glatopa 40 mg, at the Leerink Partners 7th Annual Global Healthcare Conference on Thursday, February 15, 2018 at 10:00 a.m. ET and as part of the Company's fourth quarter and year end 2017 financial results conference call on Wednesday, February 21, 2018 at 10:00 a.m. ET. A live webcast of both events will be available on the "Investors" section of the company's website, www.momentapharma.com.

About Glatopa® 40 mg/mL (glatiramer acetate injection)

Glatopa 40 mg/mL, developed in collaboration with Sandoz, is a FDA-approved generic version of three times-a-week COPAXONE® 40 mg/mL for patients with relapsing forms of multiple sclerosis (MS). Produced entirely in the United States, Glatopa 40 mg/mL has been determined by the FDA to be therapeutically equivalent to three times-a-week COPAXONE 40 mg/mL, and is an "AP" rated, fully-substitutable product. As a therapeutically equivalent generic product, Glatopa 40 mg/mL contains the same active ingredients, route of administration, strength, and dosage form, and can be substituted with the full expectation that Glatopa 40 mg/mL will produce the same clinical effect and safety profile as three times-a-week COPAXONE 40 mg/mL. Three times-a-week COPAXONE 40 mg/mL is one of the leading products marketed to treat MS, and is frequently prescribed as a first-line therapy in newly diagnosed patients.

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.

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Forward Looking Statement

Statements in this press release regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects, including statements relating to its beliefs and intentions related to Glatopa, including those about distribution and commercialization and statements regarding pricing of Glatopa are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may contain such words as "potential," "look forward," "expected" or similar terms. Such forward-looking statements involve known and unknown risks, uncertainties and other factors referred to in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 filed with the Securities and Exchange Commission under the section "Risk Factors," as well as other documents that may be filed by Momenta 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. Momenta is providing the information in this press release as of the date of this press release 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.

COPAXONE is a registered trademark of Teva Pharmaceuticals. Glatopa is a registered trademark of Novartis AG.

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