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Baxalta and Momenta Announce Initiation of Pivotal Clinical Trial for M923, a Biosimilar Version of HUMIRA (adalimumab)

Pivotal Trial of M923 in Chronic Plaque Psoriasis to Support E.U. and U.S. Registrations

BANNOCKBURN, Ill. and CAMBRIDGE, Mass., Oct. 05, 2015 (GLOBE NEWSWIRE) -- Baxalta Incorporated (NYSE:BXLT) and Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), today announced the initiation of a pivotal clinical trial in patients with chronic plaque psoriasis for M923, a biosimilar version of HUMIRA® (adalimumab). The trial is a randomized, double blind, active control, multi-center, global study in patients with chronic plaque psoriasis to compare the safety, efficacy and immunogenicity of M923 with HUMIRA. The companies are targeting first regulatory submission in 2017 and a first commercial launch in 2018.

"We are committed to expanding treatment access and providing additional options for patients who suffer from chronic plaque psoriasis," said Dagmar Rosa-Bjorkeson, executive vice president and president, Biosimilars, Baxalta. "Chronic plaque psoriasis is a debilitating disease that can have a significant impact on a patient's quality of life and physical wellbeing. We look forward to bringing a high-quality and cost-effective biosimilar version of adalimumab to patients around the world."

Baxalta Full Color Logo jpeg.jpg

Chronic plaque psoriasis is the most common form of psoriasis that affects one to three percent of the general population[1]. It is characterized by scaly plaques or lesions on the body and the scalp, which may itch or sting, and can bleed when injured. Though there are treatments available, there is no cure for psoriasis.

"We believe that our extensive analytical and biocharacterization work has allowed us to create a high-quality biosimilar candidate of HUMIRA," said Jim Roach, M.D., Senior Vice President of Development and Chief Medical Officer of Momenta Pharmaceuticals. "We look forward to progressing M923 toward regulatory approval and commercialization with our collaborative partner Baxalta and to the potential of providing a more affordable biosimilar option for the many patients suffering from chronic autoimmune and inflammatory diseases."

This milestone is part of a global collaboration between Baxalta and Momenta to develop and commercialize M923. With this collaboration, Baxalta leverages its leading clinical development, biologic manufacturing expertise, and global commercial capabilities, while Momenta provides its expertise in high-resolution analytics, characterization, clinical and regulatory strategy for complex products, and product and process development.

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

M923 is developed in collaboration by Momenta and Baxalta Incorporated. 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 and plaque psoriasis.

About Baxalta

Baxalta Incorporated (NYSE:BXLT) is a $6 billion global biopharmaceutical leader developing, manufacturing and commercializing therapies for orphan diseases and underserved conditions in hematology, oncology and immunology. Driven by passion to make a meaningful impact on patients' lives, Baxalta's broad and diverse pipeline includes biologics with novel mechanisms and advanced technology platforms such as gene therapy. The Baxalta Global Innovation and R&D Center is located in Cambridge, Massachusetts. Launched in 2015 following separation from Baxter International, Baxalta's heritage in biopharmaceuticals spans decades. Baxalta's therapies are available in more than 100 countries and it has advanced biological manufacturing operations across 12 facilities, including state-of-the-art recombinant production and plasma fractionation. Headquartered in Northern Illinois, Baxalta employs 16,000 employees worldwide.

Forward Looking Statements For Baxalta

This release includes forward-looking statements concerning M923, a proposed biosimilar of HUMIRA, including expectations with regard to clinical trials, future regulatory actions and commercialization plans, and its potential impact on patients. Such statements are made of the date that they were first issued and are based on current expectations, beliefs and assumptions of management. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Baxalta's control and which could cause actual results to differ materially from those in the forward-looking statements, including the following: clinical trial results; satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; product quality, manufacturing or supply issues; patient safety issues; and other risks identified in Baxalta's Registration Statement on Form 10 and other Securities and Exchange Commission filings, all of which are available on Baxalta's website. Baxalta expressly disclaims any intent or obligation to update these forward-looking statements except as required by law.

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 oncology and 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 Statement For Momenta Pharmaceuticals

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 progressing M923 toward regulatory approval and commercialization; timing of regulatory submissions and commercial launch; the indications for which M923 may be approved and marketed; the cost-effectiveness of M923; and the market potential for M923. Forward-looking statements may be identified by words such as "anticipate," "believe," "continue," "could," "hope," "target," "project," "goal," "objective," "guidance," "plan," "potential," "predict," "might," "estimate," "expect," "intend," "may," "seek", "should," "will," "would," "look forward" 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, 2015 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.

References

1. Naldi, L and Rzany, B. Psoriasis (chronic plaque). British Medical Journal of Clinical Evidence. 2009 Jan 9; 1706.

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