BAUSCH Health

Valeant Receives FDA Approval Of SILIQ™ (Brodalumab) For Moderate-To-Severe Plaque Psoriasis

February 16, 2017

LAVAL, Quebec , Feb. 16, 2017 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) ("Valeant" or the "Company") today announced that the U.S. Food and Drug Administration (FDA) has approved the Biologics License Application (BLA) for SILIQ™ (brodalumab) injection, for subcutaneous use, a monoclonal antibody that targets the IL-17 receptor for patients with moderate-to-severe plaque psoriasis. SILIQ is indicated for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies. Valeant expects to commence sales and marketing of SILIQ in the U.S. in the second half of 2017.

"We believe SILIQ fulfills a significant unmet medical need, and I am proud of our team's success in developing and bringing to market this treatment for patients with moderate-to-severe plaque psoriasis," said Joseph C. Papa, Chairman and CEO of Valeant. "We are pleased that SILIQ will soon be available to help treat the suffering of adults who live with this debilitating, incurable condition, and further our mission to improve people's lives with our healthcare products."

SILIQ has a Black Box Warning for the risks in patients with a history of suicidal thoughts or behavior. SILIQ was approved with a Risk Evaluation and Mitigation Strategy (REMS) involving a one-time enrollment for physicians and one-time informed consent for patients. The most common adverse reactions were headache, arthralgia, fatigue, oropharyngeal pain, and diarrhea. SILIQ is contraindicated in patients with Crohn's disease. Suicidal ideation and behavior have been reported. Serious infections have occurred therefore caution should be exercised when considering the use of SILIQ in patients with a chronic infection or a history of recurrent infection. Patients should be evaluated for tuberculosis infection prior to initiating treatment.

Plaque psoriasis is the most common type of psoriasis, a chronic, noncommunicable, skin disease.[1] The disease alters the life cycle of skin cells, causing them to build up rapidly on the surface of the skin. SILIQ works by binding to IL-17RA with high affinity, therefore blocking the inflammatory downstream activity of IL-17A, IL-17F, IL-17A/F heterodimer and IL-17E. By targeting the IL-17 receptor, SILIQ prevents skin cells from accumulating. In three clinical studies that have been completed, more than 50% of patients who used SILIQ achieved total skin clearance within a year.

"SILIQ is the only product that has demonstrated 100% improvement in the psoriasis area and severity index (PASI 100) during clinical trials as a primary endpoint," said Lawrence J. Green, M.D., associate clinical professor of Dermatology at George Washington University School of Medicine in Washington, D.C. "As the first IL-17 receptor A blocker that helps stop the proinflammatory cascade that leads to psoriasis, resulting in the normalization of skin inflammation, this is a significant achievement for the many patients who suffer with moderate-to-severe plaque psoriasis. SILIQ will be a welcomed addition to my treatment armamentarium."

"As one of the millions of people who has lived with the pain and stigma of this lifelong chronic condition, I am thrilled that SILIQ will be available as a treatment option for patients suffering with moderate-to-severe plaque psoriasis," said Tena Brown, CEO of Tenacity Consulting and Patient Advocate. "Achieving total skin clearance is a major factor in improving quality of life for patients with severe plaque psoriasis. I look forward to helping educate physicians and patients about this important and effective new treatment."

As previously announced, the Marketing Authorisation Application (MAA) for brodalumab in moderate-to-severe psoriasis was accepted by the European Medicines Agency (EMA) in the fourth quarter of 2015. In August 2015, Valeant entered into a collaboration agreement with AstraZeneca (AZN.LN, NYSE:AZN) granting Valeant an exclusive license to develop and commercialize SILIQ globally, except in Japan and certain other Asian countries where rights are held by Kyowa Hakko Kirin Co., Ltd. In July 2016, AstraZeneca and Valeant amended Valeant's license for brodalumab to terminate Valeant's right to develop and commercialize brodalumab in Europe. LEO Pharma currently holds exclusive rights to develop and commercialize brodalumab in Europe, and Valeant holds the license to develop and commercialize SILIQ in the U.S and other territories, other than Japan and certain other Asian countries. In July 2016, brodalumab (marketed as LUMICEF) was granted approval from the Ministry of Health, Labour and Welfare Japan.

About SILIQ

SILIQ is a novel human monoclonal antibody that binds to the interleukin-17 (IL-17) receptor and inhibits inflammatory signaling by preventing the binding of several types of IL-17 to the receptor. By blocking IL-17 from activating the receptor, SILIQ prevents the body from receiving signals that may lead to inflammation. The IL-17 pathway plays a central role in inducing and promoting inflammatory disease processes.

About Valeant

Valeant Pharmaceuticals International, Inc. (NYSE/TSX:VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, gastrointestinal disorders, eye health, neurology and branded generics. More information about Valeant can be found at www.valeant.com
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About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit
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Forward-looking Statements

This press release may contain forward-looking statements which may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to

differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, risks and uncertainties discussed in the Company's most recent annual or quarterly report and detailed from time to time in Valeant's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Valeant undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this press release or to reflect actual outcomes, unless required by law.

[1] Source: Global Report on Psoriasis, World Health Organization.

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