BAUSCH Health

FDA Advisory Committee Recommends Approval Of Brodalumab For Treatment Of Moderate-To-Severe Plaque Psoriasis

July 19, 2016

LAVAL, Quebec, July 19, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) today announced that the Dermatologic and Ophthalmic Drugs Advisory Committee appointed by the U.S. Food and Drug Administration (FDA) has voted by a margin of 18 to 0 for the approval of brodalumab injection, 210 mg, for adult patients with moderate-to-severe plaque psoriasis with conditions related to product labeling and post-marketing/risk management obligations.

The committee's recommendation will be considered by the FDA in its review of the Biologics License Applications (BLA) for brodalumab, a monoclonal antibody that targets the IL-17 receptor. As previously announced, the FDA assigned a Prescription Drug User Fee Act (PDUFA) action date of November 16, 2016.

"The positive recommendation by the FDA's advisory committee represents an important milestone toward our goal of delivering brodalumab to patients who suffer from moderate-to-severe plaque psoriasis," said Joseph C. Papa, chairman and chief executive officer. "Brodalumab has the potential to improve the lives of many patients suffering from this chronic, debilitating disease, and we greatly appreciated the opportunity to present our body of evidence to the panel. We look forward to working collaboratively with the FDA as it continues its review process."

"Brodalumab is an extraordinary drug that has meaningfully improved the quality of life of some of my most difficult-to-treat psoriasis patients, many of whom achieved complete skin clearance with this treatment," said Dr. Mark Lebwohl, Chairman, Department of Dermatology, Mount Sinai School of Medicine. "I am very pleased that the Advisory Committee has recommended that this life-changing treatment should be available to psoriasis patients who require a treatment with brodalumab's unique mechanism of action, and I look forward to prescribing this therapy to patients who are suffering from the devastating effects of moderate to severe plaque psoriasis."

As previously announced, the Marketing Authorisation Application (MAA) for brodalumab in psoriasis was accepted by the European Medicines Agency (EMA) in Q42015. In August 2015, Valeant entered into a collaboration agreement with AstraZeneca (AZN.LN, NYSE:AZN) granting Valeant an exclusive license to develop and commercialize brodalumab 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 brodalumab in the U.S and other territories, other than Japan and certain other Asian countries. In July 2016, brodalumab was granted approval from the Ministry of Health, Labour and Welfare Japan.

About brodalumab
Brodalumab is a novel human monoclonal antibody that binds to the interleukin-17 (IL-17)

receptor and inhibits inflammatory signaling by blocking the binding of several types of IL-17 to the receptor. By stopping IL-17 from activating the receptor, brodalumab 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.

Safety Information
The most common adverse reactions were headache, arthralgia, fatigue, oropharyngeal pain, and diarrhea. Caution should be exercised when prescribing to patients with a history of Crohn's disease. Suicidal ideation and behavior have been reported. The potential risks and benefits should be weighed before using brodalumab in patients with a history of depression and/or suicidal ideation or behavior. Serious infections have occurred therefore caution should be exercised when considering the use of brodalumab in patients with a chronic infection or a history of recurrent infection. Patients should be evaluated for tuberculosis infection prior to initiating treatment.

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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Forward-looking Statements
This press release contains forward-looking statements, including, but not limited to, statements respecting the potential of brodalumab and its review and approval by the FDA. Forward-looking statements 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 and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. 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.

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