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Valeant To Participate In FDA Advisory Committee Meeting On July 19

June 09, 2016

Committee to Review Valeant's BLA 761032 Brodalumab Subcutaneous Injection For Treatment of Adult Patients with Moderate to Severe Plaque Psoriasis

LAVAL, Quebec, June 9, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) ("Valeant" or the "Company") today announced that it has received notification from the U.S. Food and Drug Administration (FDA) that the Dermatologic and Ophthalmic Drugs Advisory Committee will review Valeant's New Drug Application (NDA) for brodalumab on July 19, 2016.

On January 25, 2016, Valeant announced that the FDA had accepted for review the Biologics License Application (BLA) submitted by AstraZeneca (LSE/SSE/NYSE: AZN) in partnership with Valeant for brodalumab injection, 210 mg, a monoclonal antibody that targets the IL-17 receptor, in development for patients with moderate to severe plaque psoriasis. The FDA assigned a Prescription Drug User Fee Act (PDUFA) action date of November 16, 2016.

"Plaque psoriasis is a chronic disease of the immune system that can impair many aspects of patients' lives," said Joseph C. Papa, chairman and chief executive officer. "We look forward to the opportunity to discuss brodalumab treatment options for adult patients with moderate to severe plaque psoriasis and provide information about this novel antibody we are developing."

As previously announced, the Marketing Authorisation Application (MAA) for brodalumab in psoriasis was accepted by the European Medicines Agency (EMA) in Q42015. In October, 2015, Valeant entered into a collaboration agreement with AstraZeneca under which Valeant has an exclusive license to develop and commercialise brodalumab globally, except in Japan and certain other Asian countries where rights are held by Kyowa Hakko Kirin Co., Ltd.

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 in the clinical development program were headache, arthralgia, fatigue, oropharyngeal pain, and diarrhea. Suicidal ideation and behavior and serious infections were reported in the clinical trials.

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 disorder, 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. 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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