

Valeant Pharmaceuticals Announces New Licensing Arrangement For Brodalumab In Europe

July 01, 2016

Valeant Receives Upfront Payment & Milestone Payments from AstraZeneca In Exchange for Termination of European Rights to Brodalumab

LAVAL, Quebec, July 1, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX:VRX) ("Valeant") today announced that its affiliate and AstraZeneca (LSE/SSE/NYSE: AZN) have amended Valeant's license for brodalumab, an IL-17 receptor monoclonal antibody under regulatory review for patients with moderate-to-severe plaque psoriasis, to terminate Valeant's right to develop and commercialize brodalumab in Europe.

In August 2015, AstraZeneca and Valeant entered into an [agreement](#)

granting Valeant an exclusive license to develop and commercialize brodalumab globally, other than in Japan and certain other Asian countries. Under the terms of the amended agreement, Valeant will continue to hold the license to develop and commercialize brodalumab in the U.S, as well as the remainder of the territory outside of Europe. As consideration for the termination of the European rights, AstraZeneca will pay to Valeant an upfront payment and certain sales-based milestone payments and, in addition, one of the pre-launch milestones payable by Valeant to AstraZeneca under the original license has been reduced.

With the termination of Valeant's licensing rights to brodalumab in Europe, AstraZeneca has entered into an agreement granting LEO Pharma the exclusive rights to develop and commercialize brodalumab in Europe.

On January 25, 2016, Valeant announced that the U.S. Food and Drug Administration (FDA) had accepted for review the Biologics License Application (BLA) submitted by AstraZeneca in partnership with Valeant for brodalumab injection for the treatment of moderate-to-severe plaque psoriasis and assigned a Prescription Drug User Fee Act (PDUFA) action date of November 16, 2016. In addition, the Dermatologic and Ophthalmic Drugs Advisory Committee will review Valeant's BLA on July 19, 2016.

"We are pleased with this new licensing arrangement for brodalumab, which enables us to more sharply focus our efforts on delivering this important treatment to patients in the U.S. and other key markets, while providing us with immediate value and significant ongoing exposure to the treatment's commercialization in Europe," said Joseph C. Papa, chairman and chief executive officer of Valeant. "Our current focus is on the upcoming advisory panel, where we will have 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."

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 studies were headache, arthralgia, fatigue, oropharyngeal pain, and diarrhea. Suicidal ideation and behavior and serious infections have been reported in the studies.

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.

Forward-looking Statements

This press release contains forward-looking statements, including, but not limited to, statements respecting the timing of the review of Valeant's BLA for brodalumab by the Dermatologic and Ophthalmic Drugs Advisory Committee, the timing and likelihood of the approval of such BLA and the anticipated benefits of brodalumab. 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. These risks and uncertainties include the risks and uncertainties discussed in Valeant'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.

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