BAUSCH Health

Valeant Announces FDA Acceptance of BLA Submission for Brodalumab in Moderate-to-Severe Plaque Psoriasis

January 25, 2016

LAVAL, Quebec, Jan. 25, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) submitted by AstraZeneca 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 has assigned a Prescription Drug User Fee Act (PDUFA) action date of November 16, 2016.

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.

The brodalumab BLA is supported by data from the three AMAGINE Phase III pivotal studies. The results highlighted that brodalumab has an effective mechanism of action that could help a significant number of moderate-to-severe plaque psoriasis patients achieve total clearance of their skin disease. At the 210 mg dose, brodalumab was shown to be effective in total skin clearance of psoriasis compared to placebo and superior to ustekinumab, a leading approved psoriasis treatment, at week 12 in two replicate comparator trials involving over 3,500 patients.

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 AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology – as well as in infection and neuroscience. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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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http://www.prnewswire.com/news-releases/valeant-announces-fda-acceptance-of-bla-submission-for-brodalumab-in-moderate-to-severe-plaque-psoriasis-300208845.html

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