BAUSCH Health

Valeant And AstraZeneca To Partner On Brodalumab

September 01, 2015

US and EU regulatory submission planned in moderate-to-severe psoriasis in Q4 2015

LAVAL, Quebec, Sept. 1, 2015 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) today announced that its affiliate has entered into a collaboration agreement with AstraZeneca under which Valeant was granted an exclusive license to develop and commercialize brodalumab.

Brodalumab is an IL-17 receptor monoclonal antibody in development for patients with moderate-to-severe plaque psoriasis and psoriatic arthritis. Under the agreement, Valeant will hold the exclusive rights to develop and commercialize brodalumab globally, except in Japan and certain other Asian countries where rights are held by Kyowa Hakko Kirin Co., Ltd under a prior arrangement with Amgen Inc., the originator of brodalumab. Valeant will assume all development costs associated with the regulatory approval for brodalumab. Regulatory submission in US and EU for brodalumab in moderate-to-severe psoriasis is planned for the fourth quarter of 2015.

Under the terms of the agreement, Valeant will make an up-front payment to AstraZeneca of $100 million, as well as additional pre-launch milestones of up to $170 million and further sales-related milestone payments of up to $175 million following launch. After approval, AstraZeneca and Valeant will share profits.

Brodalumab is supported by data from the three AMAGINE Phase III pivotal studies. The results highlighted that brodalumab has an effective mechanism of action that delivers clinical benefit and 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 efficacious in total skin clearance of psoriasis compared to placebo and superior to ustekinumab at week 12 in two replicate comparator trials involving over 3,500 patients.

Pascal Soriot, Chief Executive Officer of AstraZeneca, said: "Our agreement will help to bring brodalumab to patients with psoriasis who need new treatment options through Valeant's expert focus on dermatology."

J. Michael Pearson , Chairman and Chief Executive Officer of Valeant, said, "We are delighted we were able to reach a licensing agreement with AstraZeneca to commercialize brodalumab, which is potentially the most efficacious therapy yet for moderate-to-severe plaque psoriasis. We remain fully committed to dermatology and will continue to advance our pipeline of internally developed and acquired products."

The transaction is expected to complete in the fourth quarter of 2015, subject to customary closing conditions, including Hart-Scott-Rodino anti-trust clearance.

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 IL-17 ligands to the receptor. By stopping IL-17 ligands 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.

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
.

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 cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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
.

Forward-looking Statements

This press release may contain forward-looking statements, including, but not limited to, statements regarding the closing of the transaction (including the timing of closing), the aggregate amount investment to be paid by Valeant, the anticipated timing of regulatory submissions, the anticipated benefits of brodalumab, and the advancement of Valeant's pipeline. 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 of management of Valeant 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 (the "SEC") 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.

Contact Information:

Laurie W. Little
949-461-6002
laurie.little@valeant.com

Media:
Renee E. Soto / Meghan Gavigan
Sard Verbinnen & Co.
212-687-8080
rsoto@sardverb.com
/
mgavigan@sardverb.com

To view the original version on PR Newswire, visit:
http://www.prnewswire.com/news-releases/valeant-and-astrazeneca-to-partner-on-brodalumab-300135737.html

SOURCE Valeant Pharmaceuticals International, Inc.

Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
848-264-0934

LEGAL NOTICE PRIVACY POLICY

EMAIL ALERTS EMAIL PAGE RSS FEED

Use of this site signifies your agreement to the Legal Notice and Privacy Policy.
©2026 Bausch Health Companies Inc. All rights reserved. MTB.0230.USA.18 V2.0

CALIFORNIA RESIDENTS: DO NOT SELL MY PERSONAL INFORMATION

Powered by SITECORE