# Valeant Announces U.S. Launch of SILIQ™ (brodalumab) Injection

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# **Dermatology Unit Is Rebranded Ortho Dermatologics**

LAVAL, Quebec, July 27, 2017 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) today announced the launch of SILIQ™ (brodalumab) Injection during the Summer American Academy of Dermatology (AAD) meeting taking place in New York from July 27-30, 2017. SILIQ, a monoclonal antibody that targets the IL-17 receptor A, is indicated for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

"With the availability of SILIQ, physicians have a novel, efficacious treatment option for their adult patients who suffer from moderate-to-severe plaque psoriasis, which can be a truly debilitating, incurable condition," said Joseph C. Papa, chairman and CEO, Valeant. "Additionally, Valeant has priced SILIQ as the lowest-priced injectable biologic psoriasis treatment in the United States and will work closely with payers to ensure patients have the best possible access to this important new treatment option."

SILIQ has a Black Box Warning for risks of suicidal ideation and behavior. SILIQ was approved with a Risk Evaluation and Mitigation Strategy (REMS) involving a one-time enrollment for physicians and one-time informed consent for patients. The most common adverse reactions were headache, arthralgia, fatigue, oropharyngeal pain and diarrhea. SILIQ is contraindicated in patients with Crohn's disease. Suicidal ideation and behavior have occurred in patients treated with SILIQ. Serious infections have occurred, therefore caution should be exercised when considering the use of SILIQ in patients with a chronic infection or a history of recurrent infection. Patients should be evaluated for tuberculosis infection prior to initiating treatment.

"As the first and only IL-17 receptor A blocker, SILIQ is the only product on the market that demonstrated 100 percent improvement in the psoriasis area and severity index (PASI 100) during the clinical trials as a primary endpoint. In the three clinical trials that have been completed, more than 50 percent of patients who used SILIQ achieved total skin clearance within a year," noted Lawrence J. Green, M.D., assistant clinical professor of Dermatology at George Washington University School of Medicine in Washington, D.C. "For my patients that have been suffering with moderate-to-severe plaque psoriasis, having SILIQ as an accessible treatment option will make a difference in their day-to-day lives."

Valeant also announced today that its dermatology unit will be renamed Ortho Dermatologics, effective immediately, under the new senior leadership team lead by Bill Humphries, executive vice president and company group chairman, Ortho Dermatologics.

"The launch of SILIQ is a fitting demonstration of our dermatologic innovation and strong commitment to physicians and their patients. Not only are we bringing a product to market that fulfills a significant unmet medical need, but the pricing of SILIQ continues to show our commitment to making our medicines affordable for the patients who need them," said Humphries. "Historically, Ortho Dermatologics was known for high connectivity and partnership

with physicians throughout their entire career, and we look forward to continuing to build upon this long-standing legacy."

## **About SILIQ**

In February 2017, the U.S. Food and Drug Administration (FDA) approved the Biologics License Application (BLA) for SILIQ, a novel human monoclonal antibody that binds to the interleukin-17 (IL-17) receptor A and inhibits inflammatory signaling by preventing the binding of several types of IL-17 to the receptor. By blocking IL-17 from activating the receptor, SILIQ 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.

In August 2015, Valeant entered into a collaboration agreement with AstraZeneca (AZN.LN, NYSE: AZN, AZN: SSE) granting Valeant an exclusive license to develop and commercialize SILIQ 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 SILIQ in the U.S., Canada and other territories, other than Japan and certain other Asian countries. In July 2016, brodalumab (marketed as LUMICEF) was granted approval from the Ministry of Health, Labour and Welfare Japan.

# **About Ortho Dermatologics**

Ortho Dermatologics, a Valeant Pharmaceuticals International, Inc. company, is one of the largest prescription dermatology businesses in the world dedicated to helping patients in the treatment of a range of therapeutic areas including actinic keratosis, acne, atopic dermatitis, cold sores, athlete's foot, nail fungus and other dermatoses. The Ortho Dermatologics portfolio includes several leading acne, anti-fungal and anti-infective products. More information can be found at www.ortho-dermatologics.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 disorders, eye health, neurology and branded generics. More information about Valeant can be found at www.valeant.com

### **Forward-looking Statements**

This press release may contain forward-looking statements which 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 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, but are not limited to, risks and uncertainties discussed in the Company'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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## **Contact Information:**

Arthur Shannon arthur.shannon@valeant.com

514-856-3855 877-281-6642 (toll free)

## **Media Contact:**

Lainie Keller

lainie.keller@valeant.com

908-927-0617

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**Investor Inquiries** 

<u>ir@bauschhealth.com</u> 877-281-6642 514-856-3855 (Canada) LEGAL NOTICE PRIVACY POLICY

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Media inquiries

Corporate.communications@bauschhealth.com

908-569-3692

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