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Ortho Dermatologics Presents An Analysis Of SILIQ™ (Brodalumab) Injection Phase 3 Data On Disease-Related Anxiety And Depression In Patients With Moderate-To-Severe Plaque Psoriasis

February 16, 2018

Separate Phase 3 Analysis Highlights Long-Term Safety Profile of SILIQ

LAVAL, Quebec, Feb. 16, 2018 – Ortho Dermatologics, a division of Valeant Pharmaceuticals North America, LLC (NYSE: VRX and TSX: VRX), today announced results from an analysis of the Phase 3 clinical trial AMAGINE-1, which evaluated mental health comorbidities associated with psoriasis, such as anxiety and depression. These findings were presented for the first time at the 76th Annual Meeting of the American Academy of Dermatology (AAD), Feb. 16-20, 2018, in San Diego.

"Anxiety and depression occur more frequently among patients with psoriasis than the general population," said Dr. Melinda Gooderham, medical director at the SKiN Centre for Dermatology in Peterborough, Ontario. "The data from AMAGINE-1 demonstrated that patients who switched from placebo to SILIQ had lower scores for disease-related anxiety and depression."

Also presented at the meeting was a pooled analysis of the Pivotal Phase 3 clinical trials AMAGINE-1, -2 and -3, which demonstrated that the safety profile of SILIQ at year two of treatment for patients with moderate-to-severe psoriasis was similar to its safety profile at year one of treatment. In total, 15 abstracts, including six oral presentations and nine poster presentations, will be presented on SILIQ.

SILIQ 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. SILIQ has a Black Box Warning and a Risk Evaluation and Mitigation Strategy (REMS) due to observed suicidal ideation and behavior in clinical trials. SILIQ is contraindicated in patients with Crohn's disease. 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 and avoid use of live vaccines.[i]

Plaque psoriasis is the most common type of psoriasis, a chronic, noncommunicable skin disease that alters the life cycle of skin cells, causing them to build up rapidly on the surface of the skin.[ii, iii, iv] It is associated with serious comorbidities and substantial impairment of physical and psychological quality of life.[iv]

"The robust research being presented at AAD continues to deepen our understanding of the potential of SILIQ and reinforces our commitment to addressing patient needs," said Bill Humphries, executive vice president of Dermatology, Ortho Dermatologics. "Plaque psoriasis is a

chronic condition that often requires lifelong management, and we are encouraged by the consistent safety profile of SILIQ during the second year of treatment."

Summary of Results

Effects of Brodalumab on Anxiety and Depression in Patients With Psoriasis: Results From a Phase 3, Randomized, Controlled Clinical Trial
Results from the Phase 3, randomized, controlled clinical trial AMAGINE-1 suggested that treatment with SILIQ reduced anxiety and depression in patients with moderate-to-severe plaque psoriasis. In the study, hospital anxiety and depression scale (HADS) scores were measured at baseline and at 12, 24, 36 and 52 weeks in patients treated with SILIQ (210 mg) or placebo. After 12 weeks of SILIQ treatment, patients experienced a decrease in depression and anxiety HADS scores (mean scores decreased by 2.1 and 1.8, respectively) while scores remained unaffected in those receiving placebo. Improvement in depression and anxiety HADS scores were also seen in patients who switched from placebo to SILIQ after a 12 week induction phase (mean scores decreased by 2.3 and 1.7, respectively), but worsened in patients who switched from SILIQ to placebo.

Long-term Safety of Brodalumab for the Treatment of Moderate-to-Severe Psoriasis: 2-Year Data From 3 Pivotal Phase 3 Clinical Trials
Results from a pooled analysis of three double-blind, placebo-controlled, Phase 3 clinical trials (AMAGINE-1, -2, and -3) demonstrated that the safety profile of SILIQ in patients with moderate-to-severe plaque psoriasis during the second year of treatment was similar to that of the first year of treatment. Additionally, no unexpected safety signals emerged. The analysis evaluated 3,708 patients who received any dose of SILIQ in the long-term, open-label extension studies of the three trials. Overall, in the second year of treatment, the most common treatment-emergent adverse events were joint pain (n=196), headache (n=155) and candida infections (n=111), and one fatal treatment-emergent adverse event (cardiac arrest) occurred.

About SILIQ
In February 2017, the U.S. Food and Drug Administration (FDA) approved the Biologics License Application 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. 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 and other territories, other than Japan and certain other Asian countries.

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
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Important Safety Information

What is the most important information I should know about SILIQ?
Suicidal thoughts or behavior: Some patients taking SILIQ have had suicidal thoughts or ended their own lives. This risk is higher if you have a history of suicidal thoughts or depression.

It is not known if SILIQ causes these thoughts or actions. Get medical help right away if you or a family member notices that you have any of the following symptoms:

- new or worsening depression, anxiety, or mood problems
- thoughts of suicide, dying, or hurting yourself
- attempt to commit suicide, or acting on dangerous impulses
- other unusual changes in your behavior or mood

Your healthcare provider will give you a SILIQ patient/wallet card about symptoms that need medical attention right away. Carry the card with you during treatment with SILIQ and show it to all of your healthcare providers.

Serious Infections: SILIQ may lower the ability of your immune system to fight infections and may increase your risk of infections.

- Your healthcare provider should check you for tuberculosis (TB) before starting treatment with SILIQ and may treat you for TB before starting SILIQ if you have TB or a history of it
- You and your healthcare provider need to watch closely for signs and symptoms of infection during treatment with SILIQ, including fever, sweats, chills, shortness of breath, stomach issues, muscle aches, cough, sore throat or trouble swallowing, warm/red painful skin sores, burning while urinating or more frequent urination

Who should not use SILIQ?

Do not use SILIQ if you have Crohn's disease. Tell your healthcare provider if you develop diarrhea, bloody stools, stomach pain or cramping, sudden or uncontrollable bowel movements, loss of appetite, constipation, weight loss, fever or tiredness as these may be symptoms of Crohn's disease.

Before starting SILIQ, tell your healthcare provider if you:

- have a history of mental health problems, including suicidal thoughts, depression, anxiety, or mood problems
- have an infection that does not go away or keeps coming back
- have TB or have been in close contact with someone with TB
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid getting live vaccines while being treated with SILIQ
- are or plan to become pregnant, or are breastfeeding or plan to do so. It is unknown if SILIQ can harm your unborn or newborn baby

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use SILIQ?

See the detailed "Instructions for Use" that come with your SILIQ for information on the right way to store, prepare, and give your SILIQ injections at home, and how to properly throw away (dispose of) used SILIQ prefilled syringes. Use SILIQ exactly as your healthcare provider tells you to use it.

What are possible side effects of SILIQ?

SILIQ may cause serious side effects. See "What is the most important information I should know about SILIQ?" and "Who should not take SILIQ?"

The **most common side effects** of SILIQ include:

Joint pain Headache Tiredness	Muscle pain Injection site reactions Flu

Diarrhea Mouth or throat pain Nausea	Low white blood cell count (neutropenia) Fungal infections of the skin

Call your doctor for medical advice on side effects. You are encouraged to report negative side effects of prescription drugs to FDA at
www.fda.gov/MedWatch
or call 1-800-FDA-1088.

Click
here
for full Prescribing Information, including Black Box Warning about suicidal ideation and behavior.

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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[i] SILIQ™ label.
[ii] National Psoriasis Foundation. (2014). About Psoriasis. Retrieved from https://www.psoriasis.org/about-psoriasis. Accessed February 6, 2018.
[iii] World Health Organization. (2016). Psoriasis. Retrieved from http://www.who.int/ncds/management/psoriasis/en/. Accessed February 6, 2018.
[iv] Mayo Clinic. (2017). Psoriasis. Retrieved from https://www.mayoclinic.org/diseases-conditions/psoriasis/symptoms-causes/syc-20355840. Accessed February 6, 2018.

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

Media inquiries
Corporate.communications@bauschhealth.com
908-569-3692