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Ortho Dermatologics Announces Two-Year Findings From Pivotal Phase 3 Study Of SILIQ™ (brodalumab) Injection Data Demonstrating Long-Term Efficacy Profile

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Data Sets Demonstrating Efficacy and Quality of Life Profile of SILIQ Presented at 2017 Fall Clinical Dermatology Conference

LAVAL, Quebec, Oct. 12, 2017 /PRNewswire/ -- Ortho Dermatologics, a division of Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX), today announced results from the Pivotal Phase 3 long-term extension study (AMAGINE-2), which demonstrated that SILIQ™ (brodalumab) injection provided sustained high levels of skin clearance (PASI 100) over more than two years in patients with moderate-to-severe psoriasis. These findings are being presented for the first time today at the 2017 Fall Clinical Dermatology Conference in Las Vegas.

"Over a two-year trial, a PASI 100 response rate was reached by 59 percent of a sub-analysis group of patients, demonstrating that SILIQ is a long-term option to treat moderate-to-severe psoriasis," stated Alan Menter, M.D. "This is highly important as patients always fear a flare-up of their psoriasis after initial clearing."

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.

"For patients with and without prior ustekinumab exposure, SILIQ demonstrated improved skin clearance," said Lawrence J. Green, M.D., associate clinical professor of Dermatology at George Washington University School of Medicine in Washington, D.C. "More than 65 percent of both ustekinumab-naïve and -experienced patients in AMAGINE-1 receiving SILIQ treatment experienced complete clearance (PASI 100) at week 52, making this an excellent solution with proven results for a wide range of patients with moderate-to-severe psoriasis."

Dr. Lawrence Green will be presenting additional information about SILIQ during a product theatre titled, "A New Mechanism of Action in the Treatment of Moderate-to-Severe Plaque Psoriasis" on Thursday, October 12th at 1pm – 2pm PT.

"I am pleased to see the durable efficacy of SILIQ demonstrated through these additional findings," said Joseph C. Papa, chairman and CEO, Valeant. "This dermatologic innovation has been shown to not only provide relief for many patients who suffer from moderate-to-severe plaque psoriasis, but also had an overall positive impact on the quality of life of these patients."

Long-term Efficacy of Brodalumab for the Treatment of Moderate-to-Severe Psoriasis Study (AMAGINE-2)
Results from the long-term extension study (AMAGINE-2) found that SILIQ provided sustained high levels of skin clearance (PASI 100) over more than two years in those with moderate-to-severe psoriasis. Further, a sub-analysis group of patients who received any dose of brodalumab in the induction phase and SILIQ during the maintenance and long-term extension (LTE) phases demonstrated similar response rates. Patients who received either study dose of brodalumab in the induction phase and SILIQ throughout the maintenance and LTE phases at week 120, had a PASI 100 response rate of 59.0% (N=178), and PASI 90 response rate of 76.4% (N=178). At week 52, the same set of patients had a PASI 100 response rate of 63.4% (N=290) and PASI 90 response rate of 85.9% (N=290). At week 120, SILIQ continued to be generally well-tolerated with a safety profile comparable to that observed in the 52-week period.

Efficacy of Brodalumab in Ustekinumab-Naive and -Experienced Patients With Moderate-to-Severe Plaque Psoriasis (AMAGINE-1) Study
Results of a phase III, multicenter, randomized, double-blind, placebo-controlled study (AMAGINE-1) of the efficacy of brodalumab in a subset of patients with prior exposure to ustekinumab, demonstrated that SILIQ was similarly efficacious with improved skin clearance in patients both with and without prior ustekinumab exposure. Among patients receiving continuous SILIQ, rates of 100% reduction in PASI score (PASI 100) was 65.2% (43 of 66) and 76.5% (n=13 of 17) in ustekinumab-naive and -experienced patients at week 52, respectively. PASI 90 were 75.8% (50 of 66) in ustekinumab-naive and 88.2% (15 of 17), in ustekinumab-experienced patients.

Impact of Brodalumab Treatment on Psoriasis Symptom Severity and Improvements in Health-Related Quality of Life Study
Psoriasis symptoms have a significant negative impact on health-related quality of life, impairing physical functioning and well-being. Previously, data has shown that treatment with SILIQ provided rapid improvement in Psoriasis Area and Severity Index (PASI) and psoriasis symptoms in patients with moderate-to-severe psoriasis. This improvement with SILIQ can also be demonstrated by comparing baseline data with measurements at week 12 in terms of improvement in psoriasis symptom inventory scores (PSI) and Dermatology Quality of Life Index (DLQI) scores, which are highly correlated. Additionally, an improvement in psoriasis symptoms inventory score correlated with decreased PASI scores with SILIQ treatment.

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 and other territories, other than Japan and certain other Asian countries.

About Ortho Dermatologics
Ortho Dermatologics 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	Muscle pain
Headache	Injection site reactions
Tiredness	Flu
Diarrhea	Low white blood cell count
Mouth or throat pain	(neutropenia)
Nausea	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.

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.

Please call 1-800-321-4576 for full Prescribing Information, including Black Box Warning about suicidal ideation and behavior, or visit
www.siliq.com

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