

Valeant Pharmaceuticals Announces FDA Approval Of ONEXTON™ Gel For The Treatment Of Acne Vulgaris

November 25, 2014

LAVAL, Quebec, Nov. 25, 2014 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) announced today that it has received approval from the Food and Drug Administration (FDA) for ONEXTON™ Gel (clindamycin phosphate and benzoyl peroxide), 1.2%/3.75%, for the once-daily treatment of comedonal (non-inflammatory) and inflammatory acne in patients 12 and older. Acne vulgaris is a common skin disorder that affects 40 to 50 million people in the United States.

"We are very pleased that the FDA has approved this new dual action medication that gives physicians and patients a new option for the topical treatment of acne vulgaris," said J. Michael Pearson, chairman and chief executive officer. "ONEXTON is the fourth product to be approved in our medical dermatology business in the past twelve months, three of which were conceived and developed entirely by Valeant's internal R&D team. This continues to validate our output driven approach to R&D. Valeant has already successfully launched Jublia® (efinaconazole) 10%, Retin-A® Micro (tretinoin gel) microsphere 0.08% and Luzu (luliconazole) 1% and we plan to launch ONEXTON™ in early 2015."

"Acne is a pervasive disease that, if left unchecked, can have significant impact for patients" said Joshua Zeichner, MD and Director of Cosmetic and Clinical Research, Department of Dermatology, Mount Sinai Hospital. "We encourage people with acne to visit a dermatologist or other healthcare professional for treatment. ONEXTON™ Gel is an effective topical medication, appropriate for patients with a wide range of acne and has a favorable tolerability profile."

Information about ONEXTON™ Gel, 1.2%/3.75%

ONEXTON™ Gel is the first and only FDA-approved fixed combination 1.2% clindamycin phosphate and 3.75% benzoyl peroxide medication for the once-daily treatment of comedonal (non-inflammatory) and inflammatory acne. ONEXTON™ Gel has a favorable cutaneous tolerability profile and contains no surfactants, alcohol or preservatives. ONEXTON™ Gel has been studied extensively prior to its approval. In a pivotal trial with 498 patients with moderate to severe acne, efficacy was assessed at week 12. ONEXTON™ Gel reduced non-inflammatory lesions by a mean of 52% vs. 28% vehicle, for mean absolute reductions of 19 vs. 10, respectively. ONEXTON™ Gel also reduced inflammatory lesions by a mean of 60% vs. 31% vehicle, for mean absolute reduction of 16 vs. 8, respectively. In addition, the proportion of patients experiencing treatment success in the ONEXTON™ group was twice that of vehicle (35% vs. 17%). Treatment success was defined as at least 2 grade improvement in the Evaluator Global Severity (EGS) score from baseline.

In the controlled clinical trial, less than 1% of patients experienced a treatment related adverse event. The most common treatment-emergent and treatment-related adverse events were: burning sensation (0.4%), dermatitis contact (0.4%), pruritus (0.4%) and rash (0.4%). No ONEXTON™ patient had their treatment discontinued due to any adverse event.

Serious side effects, including inflammation of the colon (colitis) and allergic reactions have been reported with the use of combination clindamycin/benzoyl peroxide products. Stop using ONEXTON™ Gel and contact your doctor right away if you have severe watery or bloody diarrhea, or if you experience severe itching; swelling of your face, eyes, lips, tongue or throat; or difficulty breathing.

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, 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, including, but not limited to, the launch of ONEXTON™ Gel (clindamycin phosphate and benzoyl peroxide), 1.2%/3.75% in early 2015. 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 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, the 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. 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, except as required by law.

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