

# Ortho Dermatologics Announces Publication Of Pivotal Efficacy And Safety Data For Psoriasis Treatment DUOBRII™ In The Journal of the American Academy of Dermatology

April 09, 2018

## **DUOBRII Demonstrated Significant Superiority Over Vehicle As Early As Two Weeks**

LAVAL, Quebec, April 9, 2018 /PRNewswire/ -- Ortho Dermatologics, a division of Valeant Pharmaceuticals North America, LLC (NYSE/TSX: VRX), today announced that the *Journal of the American Academy of Dermatology (JAAD)* published for the first time positive results from two Phase 3, multicenter, randomized, double-blind clinical trials (Studies 1 and 2) to assess the safety and efficacy of DUOBRII™<sup>1</sup> (halobetasol propionate and tazarotene) (IDP-118) lotion in the treatment of plaque psoriasis.<sup>2</sup>

Studies 1 and 2, which enrolled a total of 418 patients, showed DUOBRII was consistently more effective than vehicle in achieving treatment success (defined as those with at least a two-grade improvement from baseline in an Investigator Global Assessment (IGA) score, and 'clear' or 'almost clear' skin), demonstrating statistically significant superiority by week four (in Study 1) and week two (in Study 2). At week eight, 35.8 percent (Study 1) and 45.3 percent (Study 2) had achieved the primary efficacy outcome, compared to 7.0 percent and 12.5 percent on vehicle (both  $p < 0.001$ ). The majority of patients maintained treatment success over the four-week post treatment period. DUOBRII was also superior in reducing psoriasis signs and symptoms and body surface area (BSA) affected compared to vehicle. In addition, DUOBRII showed significant reductions in the severity of the clinical signs of psoriasis. The most common treatment-related adverse events were contact dermatitis (6.3 percent), application site pain (2.6 percent) and pruritus (2.2 percent).

"I've found that psoriasis patients may benefit from combination therapy with topical agents, many of whom are unsatisfied with current treatment options," said Linda Stein Gold, M.D., director, Dermatology Clinical Research, Henry Ford Health System. "DUOBRII is a fixed dose combination of halobetasol and tazarotene that has shown synergistic efficacy in the Phase 2 study. Efficacy was again demonstrated in the two Phase 3 studies versus vehicle with minimal side effects in a well-tolerated, patient preferred formulation."

Halobetasol propionate and tazarotene, when used separately to treat plaque psoriasis, are limited to a four-week or less duration of use and a high rate of adverse events, respectively. Based on existing data from these and other clinical studies, the combination of these ingredients in DUOBRII with a dual mechanism of action, potentially allows for expanded duration of use, with a proven safety profile.

"Topical corticosteroid treatments are a cornerstone of psoriasis treatment, but safety concerns have limited their duration of use for many patients. If approved, DUOBRII will be the first and only topical lotion that contains a unique combination of halobetasol propionate and tazarotene in one formulation," said Bill Humphries, executive vice president, Dermatology, Ortho Dermatologics. "We are excited by the hope of what DUOBRII may offer patients, and we are

committed to working with regulatory authorities to bring this potential new treatment option to market as quickly as possible."

The U.S. Food and Drug Administration has accepted the New Drug Application for DUOBRII lotion with a Prescription Drug User Fee Act (PDUFA) action date of June 18, 2018.

### **About the Phase 3 Studies (Study 1 and Study 2)**

Study 1 and Study 2 were two multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies. The studies evaluated the effectiveness of DUOBRII, compared to vehicle among 418 patients 18 years of age and older with an IGA score of three or four, and affected BSA of three to 12 percent.

Patients were randomized 2:1 to receive DUOBRII or vehicle once-daily for eight weeks, with a follow-up at four weeks after discontinuation of active treatment. The primary efficacy endpoint was the percent of patients who showed treatment success at week eight (defined as those with at least a two-grade improvement from baseline in IGA score, and 'clear' or 'almost clear' skin). IGA was assessed by the investigator using a five-point scale ranging from zero (clear) to four (severe) at each study visit. Secondary efficacy data were provided at weeks two, four, six, and week 12. Safety and treatment emergent adverse events were evaluated throughout.

### **About DUOBRII**

DUOBRII (halobetasol propionate and tazarotene) (IDP-118) lotion is an investigational topical treatment for plaque psoriasis. If approved, DUOBRII will be the first and only topical lotion that contains a unique combination of halobetasol propionate and tazarotene in one formulation for the treatment of plaque psoriasis in adult patients.

### **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 psoriasis, actinic keratosis, acne, atopic dermatitis 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](http://www.ortho-dermatologics.com)

### **About Valeant**

Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at [www.valeant.com](http://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.

<sup>1</sup>Provisional Name

<sup>2</sup> Bulley, et al. "Safety and Efficacy of a Halobetasol/Tazarotene Fixed Combination in the Treatment of Moderate-to-Severe Plaque Psoriasis: Results of Two Phase 3 Randomized Controlled Trials." *Journal of the American Academy of Dermatology*.

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