

# Valeant Pharmaceuticals Announces Phase 3 Results For Psoriasis Treatment IDP-118

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LAVAL, Quebec, Dec. 8, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) ("Valeant") today announced positive results from a Phase 3, multicenter double-blind, randomized, vehicle-controlled clinical study to assess the safety and efficacy of IDP-118 (halobetasol propionate and tazarotene) lotion in the treatment of plaque psoriasis.

Within the Phase 3 study of 215 adult subjects with moderate to severe psoriasis, IDP-118 showed statistical significance to vehicle with a treatment success rate of 45.33% and a  $p < 0.001$ . The primary endpoint of the 12-week study was achievement of a "clear" to "almost clear" score based on an Investigator Global Assessment (IGA) at 8 weeks, and at least 2 grade improvement in the IGA at weeks 12, 6, 4 and 2 as secondary endpoints.

"We are pleased to share the positive results from the Phase 3 study of this important new formulation," stated Joseph C. Papa, Chairman and Chief Executive Officer. "Psoriasis is often difficult to treat, and dealing with this life-long condition can significantly impact a patient's quality of life. Valeant remains committed to continued research into innovative new treatments to improve the lives of those who suffer from psoriasis."

While halobetasol propionate and tazarotene are both approved and used to treat plaque psoriasis, each has certain attributes that can influence the treatment duration owing to potential adverse events. Based on existing data from our clinical studies, the combination of these ingredients in IDP-118 with a dual mechanism of action potentially allows for expanded use of these active ingredients with reduced adverse events.

The Phase 3 program was preceded by a successful Phase 2 study where the combination product IDP-118, with a treatment success rate of 52.5%, was superior to each of the actives halobetasol propionate and tazarotene as well as the vehicle. Valeant expects to have data from a second confirmatory pivotal Phase 3 study in 2017.

## **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](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.

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