

# Ortho Dermatologics Announces U.S. FDA Filing Acceptance For IDP-121 Acne Treatment In Lotion Form

January 12, 2018

## **PDUFA Date Is Aug. 27, 2018**

LAVAL, Quebec, Jan. 12, 2018 /PRNewswire/ -- Ortho Dermatologics, a division of Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) ("Valeant") , today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application for IDP-121 (tretinoin 0.05%) lotion (ALTRENO™<sup>1</sup>) with a PDUFA action date of Aug. 27, 2018. If approved, ALTRENO will be the first tretinoin product in lotion form rather than a gel or cream.

"More than 4 million patients make appointments with dermatologists each year for acne. It is our goal to be the go-to resource for doctors and patients for all dermatological conditions, and if approved, ALTRENO will be a valuable addition to the Ortho Dermatologics portfolio," said Joseph C. Papa, chairman and CEO, Valeant.

Acne, also known as acne vulgaris, is the most common skin disease in the United States, and as many as 50 million people in the United States may have the disease.<sup>2</sup>

## **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 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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<sup>1</sup> Provisional name

<sup>2</sup> White GM. Recent findings in the epidemiologic evidence, classification, and subtypes of acne vulgaris. J Am Acad Dermatol. 2004;39:S34-37



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<http://www.prnewswire.com/news-releases/ortho-dermatologics-announces-us-fda-filing-acceptance-for-idp-121-acne-treatment-in-lotion-form-300581762.html>

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