Ortho Dermatologics Announces U.S. FDA Filing Acceptance For IDP-118, Novel Plaque Psoriasis Treatment

November 02, 2017

LAVAL, Quebec, Nov. 2, 2017 /PRNewswire/ -- Ortho Dermatologics, a division of Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX), today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for IDP-118 (halobetasol propionate and tazarotene) lotion, an investigational topical treatment for plaque psoriasis. The PDUFA action date is June 18, 2018.

If approved, IDP-118 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, allowing for a potentially expanded duration of use.

The most common adverse events were contact dermatitis (7.4%) and application site pain (2.6%).

About Ortho Dermatologics

Ortho Dermatologics, a Valeant Pharmaceuticals International, Inc. company, is one of the largest prescription dermatology companies in the world dedicated to helping patients in the treatment of a range of therapeutic areas including actinic keratosis, acne, atopic dermatitis, psoriasis, 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

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

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 the management of Valeant and Nicox 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 Valeant'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. Neither Valeant nor Nicox undertakes any 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.

Investor Contact:	Media Contact:
Arthur Shannon	Lainie Keller
arthur.shannon@valeant.com	lainie.keller@valeant.com
514-856-3855	908-927-0617
877-281-6642 (toll free)	

View original content with multimedia:

http://www.prnewswire.com/news-releases/ortho-dermatologics-announces-us-fda-filing-accepta nce-for-idp-118-novel-plaque-psoriasis-treatment-300548118.html

SOURCE Valeant Pharmaceuticals International, Inc.





Investor Inquiries

<u>ir@bauschhealth.com</u> 877-281-6642 514-856-3855 (Canada) LEGAL NOTICE PRIVACY POLICY

EMAIL ALERTS

EMAIL PAGE

RSS FEED

Media inquiries

<u>Corporate.communications@bauschhealth.com</u> 908-569-3692

Use of this site signifies your agreement to the Legal Notice and Privacy Policy. ©2025 Bausch Health Companies Inc. All rights reserved. MTB.0230.USA.18 V2.0

CALIFORNIA RESIDENTS: <u>DO NOT SELL MY</u>
<u>PERSONAL INFORMATION</u>

