BAUSCH Health

Ortho Dermatologics Submits New Drug Application To The U.S. Food And Drug Administration For Psoriasis Treatment IDP-118

September 05, 2017

Novel Investigational Topical Lotion with Unique Formulation Targets the Treatment of Plaque Psoriasis

LAVAL, Quebec, Sept. 5, 2017 /PRNewswire/ -- Ortho Dermatologics, a division of Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX), today announced it has

submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for IDP-118 (halobetasol propionate and tazarotene) lotion. IDP-118 is the first and only topical lotion that contains a unique combination of halobetasol propionate and tazarotene for the treatment of plaque psoriasis.

"We are greatly encouraged by the efficacy and safety results of the IDP-118 clinical program and proud of the dedication of our medical and R&D teams who were able to expedite the NDA filing ahead of internal expectations for this promising treatment," said Joseph C. Papa, chairman and CEO, Valeant. "This submission reflects our unwavering commitment to investing in our pipeline to bring forward novel treatment innovations that help improve the lives of our customers and their patients."

Both approved to treat plaque psoriasis, halobetasol propionate and tazarotene, when used separately, are limited to a four-week or less duration of use. Based on existing data from clinical studies, the combination of these ingredients in IDP-118 with a dual mechanism of action, potentially allows for expanded duration of use, with reduced adverse events.

The NDA submitted for IDP-118 includes data from two successful Phase 3 multi-center, randomized, double-blind clinical trials in 418 subjects 18 years of age and older with 3%-12% clinical involvement of the body surface area for plaque psoriasis. In both studies, IDP-118 met the primary efficacy endpoint achieving a "clear" to "almost clear" score and at least a 2 grade improvement based on an Investigator Global Assessment (IGA) at 8 weeks, and clear to almost clear and at least 2 grade improvement during a 4 week follow up visit at week 12. The NDA also includes a long-term safety study with patients followed for one year. The most common adverse events were contact dermatitis (7.4%) and application site pain (2.6%).

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, which demonstrates the IDP-118 formulation is superior to using the individual actives separately.

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 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.

Contact Information:	**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-submits-new-drug-application-to-the-us-food-and-drug-administration-for-psoriasis-treatment-idp-118-300513782.html

SOURCE Valeant Pharmaceuticals International, Inc.

Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
848-264-0934

LEGAL NOTICE PRIVACY POLICY

EMAIL ALERTS EMAIL PAGE RSS FEED

Use of this site signifies your agreement to the Legal Notice and Privacy Policy.
©2026 Bausch Health Companies Inc. All rights reserved. MTB.0230.USA.18 V2.0

CALIFORNIA RESIDENTS: DO NOT SELL MY PERSONAL INFORMATION

Powered by SITECORE