

# FDA Issues Complete Response Letter For DUOBRII™ (Halobetasol Propionate and Tazarotene) Lotion

June 18, 2018

LAVAL, Quebec, June 18, 2018 /PRNewswire/ -- Ortho Dermatologics, a division of Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX), today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the company's New Drug Application (NDA) for DUOBRII™<sup>1</sup> (halobetasol propionate and tazarotene) (IDP-118) lotion in the treatment of plaque psoriasis.

"The CRL did not specify any deficiencies related to the clinical efficacy or safety of DUOBRII and no issues with CMC\* processes. The CRL only noted questions regarding pharmacokinetic data," said Joseph C. Papa, chairman and CEO, Valeant. "We are working to resolve this matter expeditiously and have already requested a meeting with the FDA. We hope to bring forward this important new treatment option for those who suffer from plaque psoriasis as quickly as possible."

## **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," "hopes," "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

\*Chemistry, Manufacturing and Controls

*DUOBRII is a trademark of Ortho Dermatologics' affiliated entities.*

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