

# Ortho Dermatologics Announces U.S. FDA Filing Acceptance For JEMDEL™ Plaque Psoriasis Treatment

February 14, 2018

## **PDUFA Date Set for Oct. 5, 2018**

## **JEMDEL Studied for Up to Eight Weeks of Use**

LAVAL, Quebec, Feb. 14, 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) accepted the New Drug Application for JEMDEL™<sup>1</sup> (halobetasol propionate 0.01%) (IDP-122) lotion with a PDUFA action date of Oct. 5, 2018. If approved, JEMDEL will be the first high-potency topical steroid treatment for plaque psoriasis with dosing for as long as eight weeks. In the clinical trials, the most common adverse event was upper respiratory tract infection.

"The impact of psoriasis can be devastating for the millions of patients who live with the pain and stigma of this lifelong chronic condition," said Joseph C. Papa, chairman and CEO, Valeant. "If approved, we believe JEMDEL will be an important option for patients with plaque psoriasis."

Psoriasis is a chronic, painful and frequently life-altering immune-mediated inflammatory skin disease associated with serious comorbidities and substantial impairment of physical and psychological quality of life. More than 75% of patients with moderate-to-severe plaque psoriasis experience significant itching, and greater than 55% report moderate or worse levels of pain.<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> World Health Organization Global Report on Psoriasis

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