

Ortho Dermatologics Resubmits U.S. New Drug Application For DUOBRII™ (halobetasol propionate and tazarotene) Lotion

August 15, 2018

LAVAL, Quebec, Aug. 15, 2018 /PRNewswire/ -- Ortho Dermatologics, a division of Bausch Health Companies Inc. (NYSE/TSX: BHC), today announced it has resubmitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for DUOBRII™¹ (halobetasol propionate and tazarotene) (IDP-118) lotion in the treatment of plaque psoriasis.

"After meeting with the FDA and understanding the additional pharmacokinetic data required for DUOBRII, we have resubmitted the NDA ahead of schedule," said Joseph C. Papa, chairman and CEO, Bausch Health. "We continue to have confidence in an approval of DUOBRII and hope to bring forward this important new treatment option for those who suffer from plaque psoriasis as quickly as possible."

If approved, DUOBRII 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.

About Ortho Dermatologics

Ortho Dermatologics, a Bausch Health 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 actinic keratosis, acne, atopic dermatitis, cold sores, athlete's foot, nail fungus and other dermatoses. The Ortho Dermatologics portfolio includes several leading acne, antifungal and anti-infective products. More information can be found at www.ortho-dermatologics.com

.

About Bausch Health

Bausch Health Companies Inc. (NYSE/TSX: BHC) 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.bauschhealth.com.

Forward-looking Statements

This news 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 the Company's other

filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. The Company believes that the material factors and assumptions reflected in these forward-looking statements are reasonable, but 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. Bausch Health undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

¹ Provisional name

DUOBRII is a trademark of Ortho Dermatologics' affiliated entities.

© 2018 Bausch Health Companies Inc.

Investor Contact:

Arthur Shannon

arthur.shannon@bauschhealth.com

(514) 856-3855

(877) 281-6642 (toll free)

Media Contact:

Kristy Marks

Kristy.Marks@bausch.com

(908) 827-0683

BAUSCH Health

Ortho | Dermatologics



View original content with multimedia:

<http://www.prnewswire.com/news-releases/ortho-dermatologics-resubmits-us-new-drug-application-for-duobrii-halobetasol-propionate-and-tazarotene-lotion-300697693.html>



Investor Inquiries

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

Media inquiries

Corporate.communications@bauschhealth.com
908-569-3692

[LEGAL NOTICE](#)

[PRIVACY POLICY](#)

[EMAIL ALERTS](#)

[EMAIL PAGE](#)

[RSS FEED](#)

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: DO NOT SELL MY PERSONAL INFORMATION

