FDA Accepts Resubmission Of New Drug Application For DuobriiTM (Halobetasol Propionate And Tazarotene) Lotion

August 29, 2018

PDUFA Action Date Set for February 15, 2019

LAVAL, Quebec, Aug. 29, 2018 /PRNewswire/ -- Ortho Dermatologics, one of the largest prescription dermatology health care businesses in the world and a division of Bausch Health Companies Inc. (NYSE/TSX: BHC), today announced that the U.S. Food and Drug Administration (FDA) has accepted the resubmitted New Drug Application (NDA) for DUOBRII^{TM1} (halobetasol propionate and tazarotene) (IDP-118) Lotion for the topical treatment of plaque psoriasis. The FDA accepted the application as a Class 2 resubmission, with a PDUFA action date of February 15, 2019.

"We are confident in our NDA resubmission for DUOBRII and unwavering in our commitment to bring this new treatment option to patients," said Bill Humphries, president, Ortho Dermatologics. "We have worked closely with the FDA to answer their questions regarding pharmacokinetic data, and we look forward to continued collaboration with the Agency through the remainder of the review process."

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 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

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,"

Page 1 of 3

"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.

¹Provisional name

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