

Ortho Dermatologics Announces U.S. FDA Filing Acceptance For IDP-123 Treatment For Acne Vulgaris In Lotion Form

August 07, 2019

PDUFA Action Date is Dec. 22, 2019

LAVAL, Quebec, Aug. 7, 2019 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) and its dermatology business, Ortho Dermatologics, one of the largest prescription dermatology health care businesses, today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for IDP-123 (tazarotene 0.045%) Lotion with a PDUFA action date of Dec. 22, 2019. If approved, IDP-123 will be the first tazarotene acne treatment available in a lotion form.

"Millions of Americans are affected by acne and, for many of these patients, it can be difficult to find a treatment that works for them," said Bill Humphries, president, Ortho Dermatologics. "If approved, IDP-123 will offer physicians and their patients a lower concentration of tazarotene in a lotion formulation, helping to further expand upon our growing portfolio of acne treatments."

The NDA submitted for IDP-123 includes data from two successfully completed Phase 3 randomized, placebo-controlled, double-blind clinical trials in 1,614 patients with moderate to severe acne. The primary efficacy endpoints included the absolute change in the mean noninflammatory and inflammatory lesion counts, the percentage of subjects who had a least a two-grade improvement from baseline to week 12 in the Evaluator Global Severity Score (EGSS) and who had "clear" or "almost clear" skin. In both Phase 3 studies, all primary efficacy endpoints were met with statistical significance ($p < .001$). IDP-123 was also shown to be well-tolerated in the clinical study population. The most common adverse events were application site pain, application site dryness and application site exfoliation.

About Acne Vulgaris

Acne is the most common skin problem in the United States, which occurs when hair follicles become plugged with oil and skin cells, often causing whiteheads, blackheads or pimples to appear on the face, forehead, chest, upper back and shoulders. Up to 50 million Americans have acne.¹ Depending on its severity, acne can cause emotional distress and scar the skin.²

About Ortho Dermatologics

Ortho Dermatologics is one of the largest prescription dermatology businesses 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 corticosteroid-responsive dermatoses 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.

References

1. American Academy of Dermatology. (2019). Skin conditions by the numbers. Retrieved from <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. Accessed April 1, 2019.
2. Mayo Clinic. (2018). Acne. Retrieved from <https://www.mayoclinic.org/diseases-conditions/acne/symptoms-causes/syc-20368047>. Accessed April 1, 2019.

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