

# Ortho Dermatologics Receives FDA Approval For ALTRENO™ (tretinoin 0.05%) Lotion For Acne

August 24, 2018

## **Demonstrated Tolerability and Efficacy of a Tretinoin in First and Only Once-Daily Lotion Formulation(1)**

LAVAL, Quebec, Aug. 24, 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 approved the New Drug Application for ALTRENO™ (tretinoin 0.05%) lotion, indicated for the topical treatment of acne vulgaris in patients 9 years of age and older. ALTRENO is the first formulation of tretinoin in a lotion, and has been shown to be effective and generally well-tolerated.<sup>1</sup> ALTRENO is expected to be available during the fourth quarter of 2018.

"Today's FDA approval of ALTRENO builds upon our strong acne portfolio, providing physicians and patients a trusted retinoid in a lotion formulated to enhance the user's experience with the inclusion of moisturizing attributes of hyaluronic acid, glycerin and collagen," said Bill Humphries, president, Ortho Dermatologics. "ALTRENO lotion spreads easily and is quickly absorbed into the skin allowing acne patients to easily incorporate this once-daily treatment into their skin care regimen."

Extensive clinical data has shown that retinoids are highly effective in treating acne and are considered a cornerstone of topical therapy. However, a common perceived barrier to their use is that treatment with retinoids is associated with skin irritation, such as dryness and peeling, and sensitivity. In clinical trials, ALTRENO lotion provided the proven efficacy of tretinoin, a retinoid, in a generally well-tolerated formulation with skin dryness, pain, swelling, irritation and peeling reported in  $\leq 4\%$  of patients.<sup>1,2</sup>

"Topical retinoids are a foundational treatment for all patients with acne, but they often cause skin irritation," said Joshua Zeichner, M.D., director, Cosmetic and Clinical Research in Dermatology, The Mount Sinai Hospital, New York City. "With the efficacy expected from a retinoid, plus a proven tolerability profile, ALTRENO will be an ideal choice for many of my patients."

### **ALTRENO Clinical Data**

ALTRENO was evaluated in two identical multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies, totaling 1,640 patients to determine its safety and efficacy. The data demonstrated that ALTRENO lotion resulted in statistically significant reductions in both inflammatory and non-inflammatory lesions compared to vehicle. In the population of patients treated in these studies, patients treated with ALTRENO saw a mean absolute reduction of 13.1 and 13.9 in inflammatory lesions in trials 1 and 2, respectively, compared to 10.6 and 10.7 in patients treated with vehicle. In addition, those treated with ALTRENO saw a mean absolute reduction of 17.8 and 21.9 in non-inflammatory lesions in trials 1 and 2, compared to 10.6 and 13.9 in patients treated with vehicle. Also at Week 12, 16.5% and 19.8% of patients in trials 1 and 2, respectively, achieved treatment success (at least a 2-grade improvement in global

severity by Evaluator Global Severity Scores and 'clear' or 'almost clear') with tretinoin 0.05% lotion, compared to only 6.9% and 12.5% with vehicle.<sup>1</sup>

The most common adverse reactions occurring in >1% of subjects and greater than vehicle were dryness, pain erythema, irritation and exfoliation. Sunscreen and protective clothing should be worn when sun exposure cannot be avoided. Use ALTRENO with caution if allergic to fish due to potential for allergenicity to fish protein.

The clinical trial data also showed patient satisfaction (as assessed by 1,396 patient satisfaction surveys completed at Week 12) was significantly greater with ALTRENO lotion by Week 12, with patient satisfaction of those treated with ALTRENO lotion increased by 53% compared to 43% with vehicle (P<0.001). Nine out of 10 patients reported that they were satisfied with their treatment. Patients in the treatment group saw a statistically significant increase in mean Acne-QoL assessments compared to vehicle; increase in mean scores from baseline to Week 12 with ALTRENO were 7.4 (self-perception, versus 6.7 for vehicle, P=0.003), 6.8 (role-emotional, versus 6.0, P=0.003), 4.8 (role-social, versus 4.6, P=0.038) and 6.5 (acne symptoms, versus 5.6, P<0.001).<sup>2</sup>

Please click

[here](#)

for full Prescribing Information.

### **About Acne Vulgaris**

Acne is a skin condition that occurs when hair follicles become plugged with oil and skin cells, often causing whiteheads, blackheads or pimples and appearing on the face, forehead, chest, upper back and shoulders. Acne is most common among people ages 12 to 24, though it can affect people of all ages. Depending on its severity, acne can cause emotional distress and scar the skin.<sup>3</sup>

Acne is the most common skin problem in the United States. Up to 50 million Americans have acne.<sup>4</sup>

### **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](http://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](http://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

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