

# Bausch Health Announces Publication Of Pivotal Phase 3 Efficacy And Safety Data On ALTRENO™ (tretinoin) Lotion, 0.05% In The Journal Of Drugs In Dermatology

October 11, 2018

## **ALTRENO Lotion Provides Statistically Significant Greater Efficacy Over Vehicle with a Favorable Safety and Tolerability Profile in Two Pivotal Clinical Trials<sup>1</sup>**

LAVAL, Quebec, Oct. 11, 2018 /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 *Journal of Drugs in Dermatology* has published results of two identical Phase 3, multicenter, randomized, double-blind, vehicle-controlled, parallel group studies examining the efficacy and safety of ALTRENO™ (tretinoin) Lotion, 0.05%, the first formulation of tretinoin, a retinoid, in a lotion indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.<sup>1</sup> The U.S. Food and Drug Administration approved the New Drug Application for ALTRENO Lotion on Aug. 24, 2018.

In the studies, ALTRENO Lotion was shown to have significantly greater efficacy compared to vehicle in achieving treatment success, which was defined as at least a two-grade improvement from baseline in a global severity by Evaluator Global Severity Score (EGSS) and 'clear' or 'almost clear' skin. By week 12, 17.7 percent of ALTRENO Lotion patients had achieved treatment success, compared to 9.3 percent of patients receiving vehicle. ALTRENO Lotion also demonstrated statistically significant reductions in both inflammatory and noninflammatory lesion counts (both  $P < .001$ ) at week 12 compared to vehicle (52.1 percent versus 41.0 percent for inflammatory lesion counts and 46.1 percent versus 29.9 percent in noninflammatory lesion counts). The most common adverse reactions were application site pain (3.1 percent), dryness (3.7 percent) and erythema (1.4 percent). ALTRENO Lotion was found to be generally well-tolerated among treatment groups.<sup>1</sup>

"Extensive clinical data have shown that topical retinoids are highly effective in acne and are recommended as the cornerstone of topical therapy; however, retinoids are perceived to have limited efficacy in inflammatory acne and that tolerability issues are barriers to their use. The results from the two Phase 3 clinical trials demonstrated that ALTRENO can provide physicians and their patients a new treatment option that significantly reduces inflammatory and noninflammatory acne lesions along with a favorable tolerability profile," said Sabrina Fabi, M.D., a dermatologist and dermatologic cosmetic surgeon from Cosmetic Laser Dermatology, San Diego, and assistant clinical professor, University of California, San Diego.

Patient satisfaction was also shown to be significantly greater with ALTRENO Lotion compared to vehicle, increasing from baseline to week 12 by 53 percent compared to 43 percent with vehicle ( $P < .001$ ), and with nine out of 10 patients reporting satisfaction with their treatment. Patient satisfaction was measured using the acne-specific quality of life (Acne-QoL) questionnaire. The 19-item Acne-QoL is a validated psychometric instrument designed for use in clinical trials.<sup>1</sup>

"Helping to make a difference in the lives of people living with skin conditions, such as acne, is the driving force behind our work at Ortho Dermatologics," said Bill Humphries, president, Ortho Dermatologics. "We believe these new data further demonstrate the value that ALTRENO Lotion provides patients with acne vulgaris, and we look forward to bringing the product to market by the end of the month."

### **About the Phase 3 Studies**

The study design consisted of two identical multicenter, randomized, double-blind, vehicle controlled, parallel-group Phase 3 studies to determine the efficacy, safety and tolerability of ALTRENO Lotion, compared to vehicle, among 1,640 patients, 9-58 years of age, with an Evaluator Global Severity Score (EGSS) score of three (moderate) or four (severe).<sup>1</sup>

Patients were randomized 1:1 to receive ALTRENO Lotion or vehicle once-daily for 12 weeks, with assessments carried out at four, eight and 12 weeks of treatment. The primary efficacy endpoint was the absolute change from baseline to week 12 in mean inflammatory and noninflammatory lesion counts, and the proportion of patients who were clear to almost clear achieved at least a two-grade reduction from baseline to week 12 in EGSS. Secondary efficacy endpoints included mean percent change from baseline to week 12 in inflammatory and noninflammatory lesion counts and the proportion of patients who achieved at least a two-grade reduction from baseline.<sup>1</sup>

Additional assessments included a patient satisfaction score (PSS) assessment, a validated acne-specific quality of life (Acne-QoL) questionnaire and an assessment of degree of shininess/oiliness of facial skin and its range of bothersomeness. Safety adverse events, which were summarized by treatment group, severity, and relationship to study medication, were evaluated throughout.<sup>1</sup>

## **IMPORTANT SAFETY INFORMATION FOR ALTRENO™ (TRETINOIN), 0.05% LOTION**

### **What is Altreno™?**

ALTRENO is a prescription medicine used on the skin (topical) to treat people with acne (blackheads, whiteheads and other pimples).

### **Important Safety Information**

It is not known if ALTRENO is safe and effective in children under 9 years of age. ALTRENO is for use on skin only. Do not use it in your eyes, mouth, or vagina

### **Before you use ALTRENO, tell your healthcare provider about all your medical conditions, including if you:**

- are allergic to fish. ALTRENO contains fish proteins. Tell your healthcare provider if you get hives or itching during treatment with ALTRENO.
- have eczema or any other skin problems.
- have a sunburn.
- are pregnant or plan to become pregnant. It is not known if ALTRENO will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ALTRENO passes into your breast milk.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. **Certain medicines, vitamins, or supplements may make your skin more sensitive to sunlight.** Also, tell your healthcare provider about any cosmetics you use, including moisturizers, creams, lotions, or products that can dry out your skin.

### **What should I avoid while using ALTRENO?**

- You should avoid sunlamps, tanning beds, and ultraviolet light during treatment with ALTRENO.
- Minimize exposure to sunlight. If you have to be in the sunlight or are sensitive to sunlight, use a sunscreen with a SPF of 15 or more and wear protective clothing and a wide-brimmed hat to cover the treated areas

### **What are the possible side effects of ALTRENO?**

**ALTRENO may have serious side effects, including skin irritation.** ALTRENO may cause irritation including skin dryness, pain, redness, excessive flaking or peeling. If you develop these symptoms, your healthcare provider may tell you to stop using ALTRENO for a while, decrease how often you use it, or stop it altogether. Avoid applying ALTRENO to skin that is affected by eczema or sunburned skin.

- These are not all the possible side effects of ALTRENO.
- Call your healthcare provider for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088.

Please click

[here](#)

for full Prescribing Information.

### **About Acne Vulgaris**

Acne is the most common skin problem in the United States 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. Up to 50 million Americans have acne.<sup>2</sup> Depending on its severity, acne can cause emotional distress and scar the skin.<sup>3</sup>

### **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 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 corticosteroid responsive dermatoses 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

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### **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

- Tying, Stephen K. et al. Novel Tretinoin 0.05% Lotion for the Once-Daily Treatment of Moderate-to-Severe Acne Vulgaris; Assessment of Efficacy and Safety in Patients Aged 9 Years and Older. *Journal of Drugs in Dermatology*. 17(10):2018. 602-609.
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