

Bausch Health Launches ALTRENO™ (tretinoin) Lotion, 0.05% In The United States

October 30, 2018

LAVAL, Quebec, Oct. 30, 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 the U.S. launch of ALTRENO™ (tretinoin) Lotion, 0.05% for the topical treatment of acne vulgaris in patients 9 years of age and older. ALTRENO Lotion is the first and only tretinoin available in a lotion for acne. ALTRENO Lotion has been shown to be effective and generally well-tolerated, and is provided in a formulation with known moisturizers hyaluronic acid, glycerin and collagen.¹

"We are proud to make ALTRENO Lotion available as a new option for acne patients, providing the trusted efficacy of a tretinoin, but in a lotion formulation that is generally well-tolerated and helps hydrate and moisturize the skin," said Bill Humphries, president, Ortho Dermatologics. "Millions of Americans are affected by acne, and the launch of ALTRENO Lotion underscores our commitment to expanding the treatment possibilities for this community."

The U.S. Food and Drug Administration approved ALTRENO Lotion on Aug. 24, 2018, based on data from two identical multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies that demonstrated ALTRENO Lotion resulted in statistically significant reductions in both inflammatory and non-inflammatory lesions compared to vehicle. 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 and clear to almost clear in acne severity by Evaluator Global Severity Score (EGSS). The most common adverse reactions, occurring in >1% of subjects and greater than vehicle, were dryness, pain, erythema, irritation and exfoliation.

"Many acne patients struggle using acne medications because they can cause irritation to the skin," said Joshua Zeichner, M.D., director, Cosmetic and Clinical Research in Dermatology, The Mount Sinai Hospital, New York City. "ALTRENO Lotion has demonstrated the efficacy of a tretinoin with a proven tolerability profile. Greater tolerability may help improve adherence to skin care regimens, which may ultimately lead to better patient outcomes."

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.² Depending on its severity, acne can cause emotional distress and scar the skin.³

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

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

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

WHAT IS ALTRENO™?

ALTRENO (tretinoin) lotion, 0.05% 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 the skin only. Do not use it in your eyes, mouth, or vagina.

What should I tell my healthcare provider before using ALTRENO?

Before you use ALTRENO, tell your healthcare provider about all of 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.** 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 an 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 cause 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.

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

You are encouraged to report negative side effects of prescription drugs. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click

[here](#)

for full Prescribing Information.

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. ALTRENO™ [prescribing information]. Bridgewater, NJ: Ortho Dermatologics.
2. American Academy of Dermatology. (2018). Skin conditions by the numbers. Retrieved from <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. Accessed August 6, 2018.
3. Mayo Clinic. (2018). Acne. Retrieved from <https://www.mayoclinic.org/diseases-conditions/acne/symptoms-causes/syc-20368047>. Accessed July 24, 2018.

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Investor Contact:

Arthur Shannon

Media Contact:

Lainie Keller

arthur.shannon@bauschhealth.com

lainie.keller@bauschhealth.com

(514) 856-3855
(877) 281-6642 (toll free)

(908) 927-0617

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Investor Inquiries

ir@bauschhealth.com

877-281-6642

514-856-3855 (Canada)

Media inquiries

Corporate.communications@bauschhealth.com

908-569-3692

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