

# FDA Approves Ortho Dermatologics' ARAZLO™ (Tazarotene) Lotion, 0.045%, For Acne Vulgaris

December 19, 2019

## First Tazarotene Acne Treatment Approved in Lotion Formulation

BRIDGEWATER, N.J., Dec. 19, 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 approved the New Drug Application for ARAZLO™ (tazarotene) Lotion, 0.045%, for the topical treatment of acne vulgaris in patients nine years of age and older.<sup>1</sup> ARAZLO is the first tazarotene acne treatment available in a lotion form, and has been shown to provide strong efficacy with favorable tolerability.



"Today's approval of ARAZLO showcases our continued commitment to expanding our acne portfolio to help the approximately 50 million Americans who are impacted by this prevalent skin condition," said Bill Humphries, president, Ortho Dermatologics. "As our fourth FDA approval in just 14 months, ARAZLO will provide dermatologists the efficacy expected of tazarotene in a new formulation that helps minimize the dryness and irritation historically associated with tazarotene use, which can cause many acne patients to discontinue treatment. We are purposely timing the launch of ARAZLO to coincide with the start of acne season in the first half of 2020."

Retinoids like tazarotene are a core component of acne treatment. However, a common barrier to their use is that treatment with retinoids is often associated with skin irritation, such as dryness.<sup>2</sup> In a head-to-head study, ARAZLO demonstrated similar efficacy as Tazorac (tazarotene) Cream 0.1% with about half the adverse events.<sup>2</sup> The most frequent adverse events reported with ARAZLO ( $\geq 1\%$ ) were application site pain, dryness, exfoliation, erythema and pruritus.<sup>1</sup>

"Many of my patients with moderate to severe acne can benefit from the efficacy of tazarotene, but struggle to stay on treatment due to tolerability issues," said Emil Tanghetti, M.D., lead ARAZLO study investigator and founder, Center for Dermatology and Laser Surgery, Sacramento, Calif. "Tazarotene has typically been reserved only for patients with severe acne, but offering it in a well-tolerated lotion formulation that includes hydrating agents can help more patients with most types of acne take advantage of its efficacy. I look forward to adding ARAZLO to my practice armamentarium."

## ARAZLO Comprehensive Clinical Data

The FDA approval for ARAZLO was based on data from two Phase 3 multicenter, randomized,

double-blind, vehicle-controlled clinical trials in 1,614 patients with moderate to severe acne. In both Phase 3 studies, all primary efficacy endpoints were met with statistical significance ( $p < .001$ ). ARAZLO was also shown to be generally well-tolerated in the clinical study population.

In a Phase 2, head-to-head study, ARAZLO and Tazorac (tazarotene) Cream 0.1% showed similar treatment success rates and similar reductions in both inflammatory and non-inflammatory lesions over 12 weeks. While there were no significant differences in patient satisfaction or quality of life between the two treatments and both were well-tolerated, there were numerically about double the number of treatment-related adverse events with Tazorac (5.6 percent with Tazorac versus 2.9 percent with ARAZLO).

### **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.<sup>3,4</sup> Up to 50 million Americans have acne.<sup>3</sup> Depending on its severity, acne can cause emotional distress and scar the skin.<sup>4</sup>

### **Important Safety Information for ARAZLO™ (tazarotene) Lotion, 0.045%**

#### **What is ARAZLO?**

ARAZLO™ (tazarotene) Lotion, 0.045% is a prescription medicine used on the skin (topical) to treat people 9 years of age and older with acne, which can include blackheads, whiteheads, and other pimples.

It is not known if ARAZLO is safe and effective in children under 9 years of age.

#### **Important Safety Information**

ARAZLO is for use on skin only. Do not use ARAZLO in your eyes, mouth, the corners of your nose, or vagina.

#### **What is the most important information I should know about ARAZLO?**

- **ARAZLO may cause birth defects if used during pregnancy.**
- **You must not be pregnant when you start using ARAZLO or become pregnant during treatment.**
- Use effective birth control during treatment.
- **Stop using ARAZLO and tell your healthcare provider right away if you become pregnant during treatment.**

**Before using ARAZLO, tell your healthcare provider about all your medical conditions, including if you:**

- have eczema or any other skin problems.
- are breastfeeding or plan to breastfeed. If you use ARAZLO while breastfeeding, use it for the shortest time needed. Do not apply ARAZLO directly to the nipple and surrounding area to avoid exposing your child to the medicine.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines can make your skin more sensitive to sunlight; ask your healthcare provider for a list of medicines if you are not sure.

Especially tell your healthcare provider about other products you use on your skin (such as benzoyl peroxide), including moisturizers, creams, lotions, or products that can dry out your skin.

**What should I avoid while using ARAZLO?**

- You should avoid sunlamps, tanning beds, and ultraviolet light during treatment with ARAZLO.
- Minimize exposure to sunlight; you could get severe sunburn.

If you have to be in the sunlight or are sensitive to sunlight, use a sunscreen with an SPF (sun protection factor) of 15 or more and wear protective clothing and a wide-brimmed hat to cover the treated areas.

- Avoid using ARAZLO on skin with eczema or sunburned skin because it may cause severe irritation.

**ARAZLO may cause side effects, including:**

**Skin irritation.** ARAZLO may cause irritation including skin dryness, pain, redness, excessive flaking or peeling. If you develop these symptoms, your healthcare provider may tell you to use a moisturizer, adjust the dosing, or completely stop treatment with ARAZLO.

These are not all the possible side effects of ARAZLO. Call your doctor for medical advice about side effects. You may report side effects to Bausch Health US, LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088.

Please click

[here](#)

for full Prescribing Information, including Patient Information.

**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](http://www.ortho-dermatologics.com)

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**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 Bausch Health's most recent annual or quarterly report and detailed from time to time in Bausch Health's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. 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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### Investor Contact:

Arthur Shannon

[arthur.shannon@bauschhealth.com](mailto:arthur.shannon@bauschhealth.com)

(514) 856-3855

(877) 281-6642 (toll free)

### Media Contact:

Lainie Keller

[lainie.keller@bauschhealth.com](mailto:lainie.keller@bauschhealth.com)

(908) 927-1198

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**Investor Inquiries**

[ir@bauschhealth.com](mailto:ir@bauschhealth.com)  
877-281-6642  
514-856-3855 (Canada)

**Media inquiries**

[Corporate.communications@bauschhealth.com](mailto:Corporate.communications@bauschhealth.com)  
908-569-3692

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