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# Ortho Dermatologics Announces Publication Of Pivotal Phase 3 Data On ARAZLO™ (tazarotene) Lotion, 0.045% In The Journal Of Drugs In Dermatology (JDD)

January 13, 2020

**ARAZLO Lotion Demonstrated Statistically Significant Superiority Over Placebo with Favorable Efficacy, Safety and Tolerability Profile**

**Post Hoc Analysis of the Two Phase 3 Studies Also Published in JDD**

BRIDGEWATER, N.J., Jan. 13, 2020 /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 (JDD)* published positive results from two large Phase 3, multicenter, double-blind, placebo-controlled clinical trials (Studies 1 and 2) demonstrating the efficacy, safety and tolerability of ARAZLO™ (tazarotene) Lotion, 0.045%, the first FDA approved tazarotene in lotion form for patients with moderate to severe acne.[1] A post hoc analysis of male patients in the two Phase 3 studies was also published by *JDD*.[2] The U.S. Food and Drug Administration (FDA) approved ARAZLO for the topical treatment of acne vulgaris in patients nine years of age and older in December 2019.

"When treating moderate to severe acne, I like to prescribe a tazarotene treatment due to the retinoid's efficacy, but find patients often struggle with tolerability issues, such as dry, irritated skin," said Emil A. Tanghetti, M.D., lead ARAZLO study investigator and founder, Center for Dermatology and Laser Surgery, Sacramento, Calif. "This newly published data sheds light on the utility of ARAZLO, a new treatment option that features the efficacy of tazarotene along with improved tolerability in a lotion vehicle, which is easily spreadable and aesthetically pleasing. I look forward to offering this treatment to my patients with acne in the coming months."

The first primary endpoint in the pivotal studies (Studies 1 and 2) was treatment success (defined as those with at least a two-grade improvement in Evaluator's Global Severity Score (EGSS), and 'clear' or 'almost clear' skin) measured at week 12. The data showed that ARAZLO was more effective, with 25.5 percent and 29.6 percent of patients achieving treatment success compared with 13.0 percent and 17.3 percent in the placebo arms of Studies 1 and 2, respectively ($p<0.001$ for both studies).[1]

The second primary endpoint in the pivotal studies was absolute reduction in inflammatory and noninflammatory lesion counts at week 12. The data from Studies 1 and 2 showed that ARAZLO was more effective than placebo, with reductions of 15.6 and 16.7 inflammatory lesion counts from baseline, compared to 12.4 and 13.4 in the placebo arms. Non-inflammatory lesion count reductions were 21.0 and 24.6 versus 16.4 and 16.6 in the placebo arms of the two studies, respectively ($p<0.001$ for both studies).[1]

In a pooled analysis of Studies 1 and 2, the most common treatment-related adverse events of ARAZLO compared to placebo were application site pain (5.3 percent vs 0.3 percent), dryness

(3.6 percent vs 0.1 percent), exfoliation (2.1 percent vs 0.0 percent) and erythema (1.8 percent vs 0.0 percent).[1]

"These data, combined with our recent FDA approval of ARAZLO, demonstrate our continued commitment to bringing treatment innovations to market that meet the ever-evolving needs of dermatologists and their patients who struggle with acne," said Bill Humphries, president, Ortho Dermatologics. "We look forward to launching the product later this year, providing dermatologists with a lower concentration of tazarotene lotion that helps effectively clear moderate to severe acne."

In addition to the results from the two Phase 3 studies, *JDD* also published results from a post hoc analysis of efficacy in both adult (18 years and older) and adolescent (less than 18 years old) male patients with moderate or severe acne from the Phase 3 studies. Overall, the post hoc analysis found that ARAZLO was more effective and better tolerated in adult males compared to adolescent males, with better results also reported compared to the overall study population.[2]

**About the Phase 3 Studies (Studies 1 and 2)**
Studies 1 and 2 were multicenter, double-blind, randomized, placebo-controlled, parallel-group Phase 3 studies. The studies evaluated the safety, tolerability and efficacy of ARAZLO™ (tazarotene) Lotion, 0.045%, in 1,614 patients with moderate or severe acne, as determined by the EGSS.

Patients were randomized to receive ARAZLO or placebo lotion, and all patients who were provided the study drug were included in the intent-to-treat (ITT) population. The co-primary endpoints were EGSS and absolute reduction in inflammatory and non-inflammatory lesion counts. Patients who had at least a two-grade reduction from baseline EGSS at week 12, and an EGSS of 'clear' or 'almost clear' were considered a treatment success. Secondary endpoints included percent change in both lesion counts from baseline at each study visit and absolute change in Acne-Specific Quality of Life questionnaire (Acne-QoL) domain scores. Safety, adverse events (AEs) and cutaneous tolerability were evaluated throughout the study.

**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.[3,4] Up to 50 million Americans have acne.[3] Depending on its severity, acne can cause emotional distress and scar the skin.[4]

**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 and aesthetics 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
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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," "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**


- Tanghetti EA, et al. Tazarotene 0.045% Lotion for Once-Daily Treatment of Moderate-to-Severe Acne Vulgaris: Results from Two Phase 3 Trials. *J Drugs Dermatol*. 2020;19(1): *doi:10.36849/JDD.2020.3977.*
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