BAUSCH Health

Ortho Dermatologics Launches ARAZLO™ (tazarotene) Lotion, 0.045%, In The United States

June 23, 2020

ARAZLO™ (tazarotene) Lotion, 0.045% is Indicated for the Topical Treatment of Acne Vulgaris in Patients Nine Years of Age and Older

LAVAL, QC, June 23, 2020 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) and its dermatology business, Ortho Dermatologics, one of the largest prescription dermatology health care businesses in the world, today announced that ARAZLO™ (tazarotene) Lotion, 0.045%, is available commercially to health care professionals in the United States this week. Approved by the U.S. Food and Drug Administration (FDA) in December 2019, ARAZLO is the first tazarotene acne treatment available in lotion formulation.

"Retinoids like tazarotene are highly effective in treating acne and considered a cornerstone of acne treatment, but often are perceived to be associated with skin irritation.[1] Clinical studies have demonstrated that ARAZLO's proprietary formulation provides the proven efficacy of a retinoid in a lotion that is more tolerable to patients than a higher concentration tazarotene," said Bill Humphries, president, Ortho Dermatologics. "Ortho Dermatologics remains committed to bringing forward new treatment options like ARAZLO to help the millions of Americans who suffer from acne."

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 and ARAZLO was associated with about half the number of adverse events and fewer treatment-related adverse events.[1]

"The novel lotion formulation of ARAZLO has been shown to be generally well-tolerated, allowing more patients with multiple types of acne to take advantage of its efficacy[1]," said Emil Tanghetti, M.D., lead ARAZLO study investigator and founder of the Center for Dermatology and Laser Surgery, Sacramento, Calif. "I am excited to offer ARAZLO to my patients and anticipate they will be pleased with their results."

ARAZLO is priced comparable to many other branded acne products indicated to treat moderate-to-severe acne vulgaris. For most eligible patients whose commercial insurance covers the product, they should have no co-pay (or $0 co-pay) when utilizing the ARAZLO coupon at participating pharmacies. Most other eligible, commercially insured patients will have a co-pay of as little as $65 through our access program.

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.[2]

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.[2] While there were no significant differences in patient satisfaction or

quality of life and both were well-tolerated, Tazorac was associated with nearly double the number of treatment-related adverse events (5.6 percent with Tazorac versus 2.9 percent with ARAZLO), the study reported.[2]

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

Important Safety Information for ARAZLOTM (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 and aesthetic 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 also includes several leading medical device systems for aesthetic applications, such as skin tightening and resurfacing, laser hair removal and preventative therapeutic skin care treatments. 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, the risks and uncertainties discussed in Bausch Health's most recent annual report on Form 10-K and detailed from time to time in Bausch Health's other filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. They also include, but are not limited to, risks and uncertainties caused by or relating to the evolving COVID-19 pandemic, and the fear of that pandemic and its potential effects, the severity, duration and future impact of which are highly uncertain and cannot be predicted, and which may have a material adverse impact on Bausch Health, including but not limited to its project development timelines, and costs (which may increase). 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, Kircik LH, Green LJ, et. Al. A Phase 2 multicenter, double-blind, randomized, vehicle- controlled clinical study to compare the safety and efficacy of a novel tazarotene 0.045% lotion and tazarotene 0.1% cream in the treatment of moderate-to-severe acne vulgaris. *J Drugs Dermatol.* 2019;18(6):542-548.
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