

# Ortho Dermatologics to Present New Data at the AAD VMX 2021, Virtual Meeting Experience

April 21, 2021

## **Six Poster Presentations Will Include New Analyses on ARAZLO<sup>®</sup>, DUOBRII<sup>®</sup> and SILIQ<sup>®</sup>**

LAVAL, Quebec, April 21, 2021 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") and its dermatology business, Ortho Dermatologics, one of the largest prescription dermatology health care businesses, today announced the presentation of six posters during the AAD VMX 2021, Virtual Meeting Experience, which takes place April 23-25, 2021.

One presentation will feature new analyses of ARAZLO<sup>®</sup> (tazarotene) Lotion, 0.045%, including new topline efficacy results from a post hoc analysis of two Phase 3 studies on participants with moderate-to-severe acne. Approved for patients nine years of age and older, ARAZLO has been commercially available since 2020. Two other presentations will highlight DUOBRII<sup>®</sup> (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045%. Both will focus on new efficacy data, with one also providing an overview of the profound effect of psoriasis on quality of life for patients. The three remaining presentations will include analyses evaluating the long-term efficacy and safety profile of SILIQ<sup>®</sup> (brodalumab) Injection. Please see below for warning about suicidal ideation and behavior with SILIQ.

"Ortho Dermatologics is committed to conducting research that further demonstrates the clinical benefits of our product portfolio," said Scott Hirsch, president, Ortho Dermatologics, and senior vice president and chief strategy officer, Bausch Health. "At this year's AAD meeting, we look forward to the opportunity to connect with dermatologists virtually to share new data on our latest acne medicine, ARAZLO, as well as new analyses on two of our prominent psoriasis medicines, DUOBRII and SILIQ."

The complete list of poster presentations that will be presented is as follows:

### **ARAZLO<sup>®</sup> (tazarotene) Lotion**

- *"Impact of Body Mass Index (BMI) on Efficacy of Three Topical Acne Treatments in Patients with Moderate-to-severe Acne."* Cook-Bolden et al.

### **DUOBRII<sup>®</sup> (halobetasol propionate and tazarotene) Lotion**

- *"Fixed-Combination Halobetasol Propionate 0.01%/Tazarotene 0.045% Lotion for the Treatment of Plaque Psoriasis in Patients with 3-5% Body Surface Area (BSA) and Poor Quality of Life (QoL)."* Stein Gold et al.
- *"Impact of Body Mass Index (BMI) on the Efficacy and Safety of Halobetasol Propionate 0.01%/Tazarotene 0.045% (HP/TAZ) lotion in patients with Plaque Psoriasis."* Lebwohl et al.

### **SILIQ<sup>®</sup> (brodalumab) Injection**

- *"Achievement of Body Surface Area Treatment Targets in Clinical Trials of Brodalumab."* Strober et al.
- *"Patient-Reported Psoriasis Symptoms Stratified by Sex and Level of Skin Clearance in Clinical Trials of Brodalumab."* Hebert et al.

- "Psoriasis Area and Severity Index Component Scores in Clinical Trials of Brodalumab." Lebwohl et al.

### **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>1,2</sup> Up to 50 million Americans have acne.<sup>2</sup> Depending on its severity, acne can cause emotional distress and scar the skin.<sup>2</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, FDA at 1-800-FDA-1088, or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

Please click

[here](#)

for full Prescribing Information, including Patient Information.

### **About Psoriasis**

Psoriasis is an immune-mediated disease that speeds up the life cycle of skin cells, causing them to build up rapidly on the surface of the skin. The extra skin cells form raised, red, scaly patches that are itchy and sometimes painful.<sup>3</sup> People with psoriasis are also reported to be at increased risk of developing other serious clinical conditions such as cardiovascular and other noncommunicable diseases and to suffer substantial impairment of physical and psychological quality of life.<sup>4</sup> Plaque psoriasis is the most common type of psoriasis.<sup>5</sup>

### **Important Safety Information for DUOBRII<sup>®</sup> (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045%**

#### **What is DUOBRII<sup>®</sup> Lotion?**

DUOBRII (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045%, is a prescription medicine used on the skin (topical) to treat adults with plaque psoriasis. It is not known if DUOBRII Lotion is safe and effective in children.

#### **Important Safety Information**

- DUOBRII Lotion is for use on the skin only; do not use it in your mouth, eyes, or vagina.

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

##### **DUOBRII Lotion may cause birth defects if used during pregnancy.**

A negative pregnancy test must be obtained before females of child-bearing age start using DUOBRII Lotion and they must use effective birth control during treatment. Begin treatment during a normal menstrual period.

##### **Stop using DUOBRII Lotion and tell your healthcare provider right away if you become pregnant while using DUOBRII Lotion.**

##### **Before you use DUOBRII Lotion, tell your healthcare provider if you:**

- have eczema or any other skin problems, including skin infections, which may need to be treated before using DUOBRII.
- have diabetes, adrenal gland problems or liver problems.
- are breastfeeding or plan to breastfeed. If you use DUOBRII and breastfeed, do not apply DUOBRII to your nipple area.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- **Especially tell your healthcare provider if you take corticosteroids by mouth or injection or use other skin products that contain corticosteroids.**
- **Ask your healthcare provider for a list of medicines that may make your skin more sensitive to sunlight.**

##### **What should I avoid during treatment with DUOBRII?**

- To avoid a severe sunburn, avoid sunlight, including sunlamps and tanning beds, as much as possible, and use sunscreen, protective clothing and a hat while in sunlight. Talk to your

healthcare provider if you get sunburn, and do not use DUOBRII Lotion until your sunburn is healed.

- Avoid using DUOBRII on skin with eczema because it may cause severe irritation.

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

- **If too much DUOBRII passes through your skin** it can cause adrenal glands to stop working
- **Cushing's syndrome**, a condition from too much exposure to the hormone cortisol
- **High blood sugar** (hyperglycemia)
- **Effects of growth and weight in children**
- **Skin irritation.** If you get too much skin irritation at the site of application, your healthcare provider may tell you to interrupt or stop using DUOBRII or to use it less often.
- **Vision problems**, including an increased chance of developing cataracts and glaucoma. Tell your healthcare provider about any vision problems during treatment.

**The most common side effects of DUOBRII Lotion include:** redness, itching, swelling, burning, stinging, application site pain, inflamed hair follicles (folliculitis), thinning of the skin (atrophy), peeling and rash. To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

Please click

[here](#)

for full Prescribing Information.

## **Important Safety Information for SILIQ (brodalumab) Injection**

### **What is SILIQ?**

SILIQ<sup>®</sup> injection is a prescription medicine used to treat adults with moderate to severe plaque psoriasis:

- who may benefit from injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light treatment) **and**
- who have tried another systemic therapy that didn't work or stopped working

It is not known if SILIQ is safe and effective in children.

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

**Suicidal thoughts or behavior:** Some patients taking SILIQ have had suicidal thoughts or ended their own lives. This risk is higher if you have a history of suicidal thoughts or depression. It is not known if SILIQ causes these thoughts or actions. Get medical help right away if you or a family member notices that you have any of the following symptoms:

- new or worsening depression, anxiety, or mood problems
- thoughts of suicide, dying, or hurting yourself
- attempt to commit suicide, or acting on dangerous impulses
- other unusual changes in your behavior or mood

Your healthcare provider will give you a SILIQ patient/wallet card about symptoms that need medical attention right away. Carry the card with you during treatment with SILIQ and show it to all of your healthcare providers.

**Serious Infections:** SILIQ may lower the ability of your immune system to fight infections and may increase your risk of infections:

- Your healthcare provider should check you for tuberculosis (TB) before starting treatment with SILIQ and may treat you for TB before starting SILIQ if you have TB or a history of it

- You and your healthcare provider need to watch closely for **signs and symptoms of infection** during treatment with SILIQ, including fever, sweats, chills, shortness of breath, stomach issues, muscle aches, cough, sore throat or trouble swallowing, warm/red/painful skin sores, burning while urinating or more frequent urination

**Who should not use SILIQ?**

Do not use SILIQ if you have Crohn's disease. Tell your healthcare provider if you develop diarrhea, bloody stools, stomach pain or cramping, sudden or uncontrollable bowel movements, loss of appetite, constipation, weight loss, fever or tiredness as these may be symptoms of Crohn's disease.

**Before starting SILIQ, tell your healthcare provider if you:**

- have a history of mental health problems, including suicidal thoughts, depression, anxiety, or mood problems
- have an infection that does not go away or keeps coming back
- have TB or have been in close contact with someone with TB
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid getting live vaccines while being treated with SILIQ
- are or plan to become pregnant, or are breastfeeding or plan to do so. It is unknown if SILIQ can harm your unborn or newborn baby

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How should I use SILIQ?**

**See the detailed "Instructions for Use"** that come with your SILIQ for information on the right way to store, prepare, and give your SILIQ injections at home, and how to properly throw away (dispose of) used SILIQ prefilled syringes. Use SILIQ exactly as your healthcare provider tells you to use it.

**What are possible side effects of SILIQ?**

SILIQ may cause serious side effects. See "What is the most important information I should know about SILIQ?" and "Who should not take SILIQ?"

The **most common side effects** of SILIQ include:

|                      |  |
|----------------------|--|
| Joint pain           | Muscle pain                              |
| Headache             | Injection site reactions                 |
| Tiredness            | Flu                                      |
| Diarrhea             | Low white blood cell count (neutropenia) |
| Mouth or throat pain | Fungal infections of the skin            |
| Nausea               |  |

Call your doctor for medical advice on side effects. You are encouraged to report negative side effects of prescription drugs to Bausch Health at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit

[www.fda.gov/medwatch](http://www.fda.gov/medwatch)

Click  
[here](#)

for accompanying full Prescribing Information, including Boxed Warning about suicidal ideation and behavior, and Medication Guide.

### **About Ortho Dermatologics**

Ortho Dermatologics is one of the largest 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 is further complemented by Solta Medical, the maker of Fraxel<sup>®</sup>, Thermage<sup>®</sup>, Clear + Brilliant<sup>®</sup> and Vaser<sup>®</sup> ultrasonic assisted liposuction for aesthetic applications. 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 [www.bauschhealth.com](http://www.bauschhealth.com)

### **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.

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