

# Ortho Dermatologics To Present New Analyses At The Virtual Fall Clinical Dermatology Conference

October 26, 2020

LAVAL, QC, Oct. 26, 2020 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) and its dermatology business, Ortho Dermatologics, one of the largest dermatology health care businesses in the world, today announced the presentation of nine posters during the virtual Fall Clinical Dermatology Conference, which takes place Oct. 29 - Nov. 1, 2020. The presentations will feature new post hoc analyses on ARAZLO™ (tazarotene) Lotion, 0.045%, DUOBRII® (halobetasol propionate and tazarotene) Lotion 0.01%/0.045%, and SILIQ® (brodalumab) injection 210 mg/1.5 ml, as well as pediatric data on JUBLIA® (efinaconazole) topical solution, 10%. Please see below for warning about suicidal ideation and behavior with SILIQ.

"At Ortho Dermatologics, we are committed to addressing the needs of people with a variety of skin conditions," said Bill Humphries, president, Ortho Dermatologics. "At the virtual Fall Clinical meeting, we will present new data on our latest acne treatment, ARAZLO, which launched in June, as well as data analyses on three key products from our psoriasis and onychomycosis portfolios, DUOBRII, SILIQ and JUBLIA. We are proud to have one of the most robust portfolios of branded dermatology prescription products available today, and we remain committed to conducting research to further demonstrate their clinical benefits and unique attributes to providers and patients."

The complete list of poster presentations that will include Ortho Dermatologics products is as follows:

## **ARAZLO™ (tazarotene) Lotion, 0.045%**

- Draelos et al. "A Comparative Clinical Demonstration of the Spreadability of Tazarotene Lotion 0.045% versus Trifarotene Cream 0.005%."
- Kircik et al. "Once Daily Polymeric Emulsion Tazarotene 0.045% Lotion for Moderate-to-Severe Acne: Pooled Phase 3 Analysis by Sex."
- Cook-Bolden et al. "Novel Polymeric Tazarotene 0.045% Lotion for Moderate-to-Severe Acne: Pooled Phase 3 Analysis by Race."

## **DUOBRII® (halobetasol propionate and tazarotene) Lotion 0.01%/0.045%**

- Leonardi et al. "Halobetasol Propionate 0.01%/Tazarotene 0.045% (HP/TAZ) Lotion for the Treatment of Plaque Psoriasis in Patients with 3-5% Body Surface Area."
- Stein Gold et al. "Long-Term Management of Moderate-to-Severe Plaque Psoriasis: Maintenance of Treatment Success Following Cessation of Fixed Combination Halobetasol Propionate 0.01% And Tazarotene 0.045% (HP/TAZ) Lotion in Patients with Baseline Body Surface Area of 6-12%."
- Stein Gold et al. "Long-term management of moderate-to-severe plaque psoriasis: maintenance of treatment success following cessation of halobetasol propionate 0.01%/tazarotene 0.045% lotion."

## **JUBLIA® (efinaconazole) topical solution, 10%**

- Eichenfield et al. "Safety, Pharmacokinetics, and Efficacy of Efinaconazole 10% Topical Solution for the Treatment of Onychomycosis in Pediatric Patients."

## **SILIQ® (brodalumab) injection 210 mg/1.5 ml**

- Lebwohl et al. "Two-Year US Pharmacovigilance Report of Brodalumab."
- Menter et al. "Rates of Complete Skin Clearance by Prior Adalimumab Response in Clinical Trials of Brodalumab."

### **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®, Thermage®, Clear + Brilliant® and Vaser® 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)

### **What is SILIQ?**

SILIQ (brodalumab) injection is indicated for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

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.

**This is not all the Important Safety Information you need to know about SILIQ. Please click**

**[here](#)**

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

### **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.**

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

- Minimize exposure to sunlight, and avoid tanning beds and ultraviolet light; you could get severe sunburn.
- 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.

#### **This is not all the Important Safety Information you need to know about ARAZLO.**

**Please click**

**[here](#)**

**for full Prescribing Information, including Patient Information.**

### **DUOBRII® Lotion Indication and Important Safety Information**

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.

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

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

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

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)

**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)

**This is not all of the Important Safety Information you need to know about DUOBRII; please click [here](#) for full Prescribing Information, including Patient Information.**

### **Important Safety Information for JUBLIA® (efinaconazole) Topical Solution, 10%**

#### **INDICATION**

JUBLIA (efinaconazole) Topical Solution, 10% is a prescription medicine used to treat fungal infections of the toenails.

#### **IMPORTANT SAFETY INFORMATION**

- JUBLIA is for use on nails and surrounding skin only. Do not use JUBLIA in your mouth, eyes, or vagina. Use it exactly as instructed by your doctor.
- The safety and efficacy of JUBLIA have not been established in children under six years old.
- Before you use JUBLIA, tell your doctor about all your medical conditions, including if you are or plan to become pregnant, are breastfeeding, or plan to breastfeed, because it is not known whether JUBLIA can harm an unborn fetus or nursing infant.
- Tell your doctor about all medications you are taking, and whether you have any other nail infections.
- JUBLIA is flammable. Avoid heat and flame while applying JUBLIA to your toenail.
- JUBLIA may cause irritation at the treated site. The most common side effects include: ingrown toenail, redness, itching, swelling, burning or stinging, blisters, and pain. Tell your doctor about any side effects that bother you or do not go away.

To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or the FDA at 1-800-FDA-1088 or visit

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

**Please click**

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Visit

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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.

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