BAUSCH Health

Ortho Dermatologics Will Present Data at the 2022 Florida Society of Dermatology Physician Assistants New Wave Dermatology Conference

April 27, 2022

Four Poster Presentations Will Include New Analyses on ARAZLO®

LAVAL, QC, April 27, 2022 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") and its dermatology business, Ortho Dermatologics, today announced the presentation of four poster presentations during the Florida Society of Dermatology Physician Assistants (FSDPA) 2022 New Wave Dermatology Conference, which will take place in Coral Gables, Fla. from April 28 - May 1, 2022. The presentations will feature new clinical data on ARAZLO® (tazarotene) lotion, 0.045%, as well as several encore presentations on DUOBRII® (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045%, JUBLIA® (efinaconazole) Topical Solution, 10%, and SILIQ® (brodalumab) Injection. Please see below for warning about suicidal ideation and behavior with SILIQ.

"At this year's New Wave Dermatology Conference, we will share new data on ARAZLO®, which is the first and only tazarotene lotion for acne that helps improve skin barrier function for acne patients," said Richard Lajoie, vice president and general manager, Ortho Dermatologics. "While there have been several studies examining the safety and efficacy of ARAZLO® for the treatment of facial acne, this is the first open label clinical study showing the safety and efficacy of using ARAZLO® in patients with truncal acne, which involves the chest, back or shoulders and affects 50% of the 50 million Americans currently living with acne.[1,2] We also look forward to sharing DUOBRII®, JUBLIA® and SILIQ® data with physician assistants attending the meeting."

Following is a complete list of titles and lead authors for each of these posters:

- *"Efficacy of Brodalumab vs Ustekinumab by Prior TNF-α Inhibitor Exposure: Post hoc Analysis of Two Phase 3 Psoriasis Studies."*Brunner et al.
- *"Long-term Management of Plaque Psoriasis: Maintenance of Treatment Success After Cessation of Fixed-Combination Halobetasol Propionate and Tazarotene Lotion."* Mangin et al.
- *"Tazarotene 0.045% Lotion for Truncal Acne: Efficacy, Safety, and Spreadability."* Kircik et al.
- "*Therapeutic Recommendations for the Treatment of Toenail Onychomycosis in the US."* Lipner et al.

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 or
www.fda.gov/medwatch
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Click
here
for full Prescribing Information, including Patient Information.

Important Safety Information for DUOBRII® (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045%

What is DUOBRII® 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
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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
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Please click
here
for full Prescribing Information, including Patient Information.

Visit
www.jubliarx.com
to learn more.

Important Safety Information for SILIQ (brodalumab) Injection

What is SILIQ?
SILIQ® 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
.

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

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.[2,3] Up to 50 million Americans have acne.[3] Depending on its severity, acne can cause emotional distress and scar the skin.[3]

About Ortho Dermatologics
Ortho Dermatologics is 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. For more information, 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," "hopes," "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, launches 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

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