BAUSCH Health

FDA Approves Bausch Health's DUOBRII™ (Halobetasol Propionate And Tazarotene) Lotion 0.01%/0.045% For Plaque Psoriasis In Adults

April 25, 2019

First and Only Topical Lotion Combining Halobetasol Propionate and Tazarotene in One Formulation[1]

Safety was Established in a Long-Term Study of Up to 24 Weeks of Continuous Use and Up to 52 Weeks of As-Needed Use[2]

LAVAL, Quebec, April 25, 2019 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) and its dermatology business, Ortho Dermatologics, one of the largest prescription dermatology health care businesses, announced today that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application for DUOBRII™ (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045%, indicated for the topical treatment of plaque psoriasis in adults.[1] DUOBRII is the first and only topical lotion that contains a unique combination of halobetasol propionate and tazarotene in one formulation. In a year-long safety study, patients used DUOBRII Lotion for up to 24 weeks of continuous use and up to 52 weeks of as-needed use.[2] DUOBRII is expected to be available in June 2019.

"With today's approval of DUOBRII, patients suffering from plaque psoriasis now have an innovative topical treatment option that uniquely combines two well-known ingredients, halobetasol propionate and tazarotene, with established safety profiles, into a single lotion featuring dual mechanisms of action," said Bill Humphries, president, Ortho Dermatologics. "Since psoriasis is a chronic skin disease, patients require continuous treatment in order to achieve optimal control of their symptoms. Now, with DUOBRII, health care professionals and their patients have a new topical treatment option that can help them achieve those long-term goals. As a result, we believe that DUOBRII has the potential to delay some patients from switching to more expensive biologic treatments, which could potentially result in health care savings."

Continued Mr. Humphries, "We remain committed to bringing forward new medicines, like DUOBRII, to add to our portfolio of topicals and biologics to meet the varying treatment needs of patients with psoriasis."

When used separately to treat plaque psoriasis, the duration of use of halobetasol propionate is limited by FDA labeling constraints and the use of tazarotene can be limited due to tolerability concerns. By combining halobetasol propionate and tazarotene in an advanced, patented once-daily moisturizing lotion, the DUOBRII formulation ensures uniform distribution, allowing for simultaneous contact with the skin surface.[1]

In the United States, approximately 7.5 million people live with psoriasis, with 80 percent having plaque psoriasis.[3] Plaque psoriasis is the most common type of psoriasis, a chronic, non-contagious skin disease that alters the life cycle of skin cells, causing them to build up rapidly on the surface of the skin.[4,5]

"DUOBRII provides the known benefits of a potent topical corticosteroid and a topical retinoid with synergistic efficacy. Combination therapy is the mainstay of topical treatment for plaque psoriasis, making DUOBRII an important new option," said Linda Stein Gold, M.D., director, Dermatology Clinical Research, Henry Ford Health System. "Although effective, topical retinoids have had limited use as monotherapy due to tolerability concerns. DUOBRII provides improved local tolerability, allowing patients to benefit from an extended duration of use."

DUOBRII Lotion is priced at $825 for a supply of a 100-gram tube, which is more than 50 percent lower than other branded topical combination products.* Additionally, through the company's access program, most eligible, commercially insured patients will have a co-pay between $25 and $40.

DUOBRII Comprehensive Clinical Data

A Phase 2 study demonstrated DUOBRII Lotion was consistently more effective than its individual agents and vehicle in achieving treatment success (defined as at least a two-grade improvement from baseline in an Investigator Global Assessment (IGA) score, and 'clear' or 'almost clear' skin) and reducing psoriasis signs of erythema, plaque elevation, and scaling at the target lesion.[6] In addition, a post-hoc analysis of the data, in which the vehicle effect was removed, showed that the efficacy of DUOBRII was superior to the aggregated results of the individual agents, supporting the synergy of the two ingredients when combined in one lotion formulation.

The safety and efficacy of the once daily use of DUOBRII for the treatment of plaque psoriasis were assessed in two Phase 3 prospective, multi-center, randomized, double-blind clinical trials in subjects 18 years and older with moderate to severe plaque psoriasis.[1]

Studies 1 and 2, which enrolled a total of 418 patients, showed DUOBRII was consistently more effective than vehicle in achieving treatment success (primary endpoint at eight weeks), demonstrating statistically significant superiority by week four (in Study 1) and week two (in Study 2). At week eight, 36 percent (Study 1) and 45 percent (Study 2) had achieved the primary efficacy outcome, compared to seven percent and 13 percent on vehicle (both $p<0.001$). The majority of responders maintained treatment success over the four-week post treatment period. The most common adverse events in clinical trials include redness, itching, swelling, burning, stinging, application site pain, inflamed hair follicles (folliculitis), thinning of the skin (atrophy), peeling and rash.[1]

A third Phase 3 multicenter, open-label study assessed the long term safety of DUOBRII over a year in subjects with plaque psoriasis. Patients were given DUOBRII once daily for eight weeks and re-evaluated every four weeks after for a year. Continuous treatment was allowed up to 24 weeks and as needed for up to 52 weeks. Treatment related adverse events > two percent were application site reactions such as itching, pain, irritation and inflamed hair follicles (folliculitis).[2]

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.[5] 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.[7] Plaque psoriasis is the most common type of psoriasis.[4]

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.

Visit
www.DUOBRIILotion.com
to learn more.

About Ortho Dermatologics
Ortho Dermatologics is one of the largest prescription dermatology businesses dedicated to helping patients in the treatment of a range of therapeutic areas including actinic keratosis, acne, atopic dermatitis, cold sores, athlete's foot, nail fungus and other dermatoses. The Ortho Dermatologics portfolio includes several leading acne, antifungal 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," "will," "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 the Company's most recent annual or quarterly report and detailed from time to time in the Company's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. The Company believes that the material factors and assumptions reflected in these forward-looking statements are reasonable, but 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.

**DUOBRII's per gram WAC cost is $8.25, which is 52.9% lower than competitor products. WAC Pricing Source: MediSpan PriceRx as of April 23, 2019.*

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