

Bausch Health Announces U.S. Launch Of BRYHALI™ (halobetasol propionate) Lotion, 0.01%, For Plaque Psoriasis In Adults

November 07, 2018

Launch Expected to Occur Later this Month Following Final FDA Approval

LAVAL, Quebec, Nov. 7, 2018 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) and its dermatology business, Ortho Dermatologics, one of the largest prescription dermatology health care businesses, today announced it expects to start distribution of BRYHALI™ (halobetasol propionate) Lotion, 0.01%, to U.S. wholesale pharmaceutical distributors later this month. The company received final approval from the U.S. Food and Drug Administration (FDA) for BRYHALI Lotion on Nov. 6, 2018. BRYHALI Lotion, which is indicated for the topical treatment of plaque psoriasis in adult patients, is a new potent to superpotent corticosteroid in a novel vehicle lotion with safety established for dosing up to eight weeks.¹

"We are proud of our efforts to make BRYHALI Lotion available as quickly as possible following final approval by the FDA," said Bill Humphries, president, Ortho Dermatologics. "In doing so, our customers and their patients now have a new topical treatment option that provides the efficacy of a high-potency steroid with tolerability and longer duration of use. We look forward to engaging physicians in their offices later this month to discuss BRYHALI Lotion and its unique attributes to help meet the needs of their patients."

BRYHALI Lotion had initially received a tentative approval from the FDA due to the pending expiration of exclusivity for a related product. The FDA approval of BRYHALI Lotion was based on data from two prospective, multicenter, randomized, double-blind clinical trials. In clinical trials, BRYHALI Lotion was applied once daily for eight weeks and shown to be generally well-tolerated with no increase in epidermal atrophy. In Study 1 and Study 2, 37 percent and 38 percent of patients, respectively, treated with BRYHALI Lotion achieved treatment success (at least a two-grade improvement from baseline in Investigator's Global Assessment (IGA) and an IGA score equating to "clear" or "almost clear") at eight weeks, compared to eight percent and 12 percent of patients treated with vehicle. Data from both trials showed that BRYHALI Lotion demonstrated significant treatment success over vehicle as early as week two (Study 1) and week four (Study 2), which continued through 12 weeks (four weeks post treatment). The most common adverse reactions, occurring in ≥ 1 percent of subjects treated with BRYHALI Lotion through week eight, were upper respiratory tract infection (2 percent), application site dermatitis (1 percent) and hyperglycemia (1 percent).¹

"BRYHALI Lotion will help address an unmet need for many plaque psoriasis patients," said Lawrence J. Green, M.D., a lead investigator on the BRYHALI Lotion Phase 3 studies and associate clinical professor of Dermatology at George Washington University School of Medicine in Washington, D.C. "Topical steroids are the most frequently used treatment for psoriasis, but come with an increased risk of adverse events and a duration of use limited to two to four weeks. With BRYHALI Lotion, I'm excited to offer my patients a topical steroid option that can be used for up to eight weeks without sacrificing tolerability, and with proven efficacy."

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.² 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.³ Plaque psoriasis is the most common type of psoriasis.⁴

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 psoriasis, actinic keratosis, acne, atopic dermatitis and other dermatoses. The Ortho Dermatologics portfolio includes several leading acne, anti-fungal and corticosteroid-responsive dermatoses products. More information can be found at 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

Important Safety Information for BRYHALI™ (halobetasol propionate) Lotion 0.01%

What is BRYHALI Lotion?

- BRYHALI™ Lotion is a prescription medicine used on the skin (topical) to treat adults with plaque psoriasis. It is not known if BRYHALI Lotion is safe and effective in children under 18 years of age.

Important Safety Information

- BRYHALI Lotion is for use on skin only. Do not use BRYHALI Lotion in your mouth, eyes, or vagina.

Before you use BRYHALI Lotion, tell your healthcare provider about all your medical conditions, including if you:

- Have had irritation or other skin reaction to a steroid medicine in the past
- Have a skin infection
- Have diabetes
- Have adrenal gland or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed. It is not known if BRYHALI Lotion passes into your breast milk. If you do breastfeed, do not apply BRYHALI Lotion to your nipple or areola to avoid getting it in your baby's mouth

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 other corticosteroids by mouth or injection, or use other products on your skin that contain corticosteroids.

What are the possible side effects of BRYHALI Lotion?

BRYHALI Lotion may cause serious side effects, including:

- A condition where your adrenal glands stop working
- Cushing's syndrome, a condition caused by too much exposure to the hormone cortisol
- High blood sugar (hyperglycemia)
- Skin reactions at the treated site
- Vision problems such as cataracts and glaucoma. Tell your doctor about any blurred vision or other vision problems during treatment
- Effects on growth and weight in children

The most common side effects of BRYHALI Lotion include: burning, stinging, itching, dryness (application site dermatitis), upper respiratory tract infection, and high blood sugar (hyperglycemia).

These are not all the possible side effects of BRYHALI Lotion.

Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please click

[here](#)

for full Prescribing Information.

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.

References

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