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ORTHO DERMATOLOGICS RECEIVES TENTATIVE FDA APPROVAL FOR BRYHALI™ (HALOBETASOL PROPIONATE) LOTION, 0.01%, FOR PLAQUE PSORIASIS IN ADULTS

In Clinical Trials, BRYHALI Lotion Demonstrated Significant Treatment Success Over Vehicle as Early as Week Two, Which Continued Through Week 12 (Four Weeks Post Treatment)[1]

New Corticosteroid Lotion Formulation with Safety Proven for Up to Eight Weeks Duration of Use[1]

Company Plans to Launch BRYHALI Lotion in November 2018 Upon Final FDA approval

RALEIGH, N.C., Oct. 8, 2018 – Ortho Dermatologics, one of the largest prescription dermatology health care businesses, today announced that the U.S. Food and Drug Administration (FDA) has provided tentative approval of the New Drug Application for BRYHALI™ (halobetasol propionate) Lotion, 0.01%, for the topical treatment of plaque psoriasis in adult patients. BRYHALI Lotion is a new potent to superpotent corticosteroid that contains 0.01 percent halobetasol propionate in a novel vehicle lotion. Its safety has been established in clinical trials with dosing for up to eight weeks with no increase in epidermal atrophy. [1] The final FDA approval for BRYHALI Lotion is pending the expiration of exclusivity for a related product, which is expected in early November 2018. The company plans to launch BRYHALI shortly thereafter, as scheduled, in November 2018.

“Our customers and their patients can benefit from this new treatment option that is expected to provide the efficacy of a high-potency steroid with tolerability and longer duration of use,” said Bill Humphries, president, Ortho Dermatologics. “Just as every psoriasis patient’s journey is different, so too are their treatment needs, which is why psoriasis is a key therapeutic focus for our business. We look forward to adding BRYHALI Lotion to our growing psoriasis portfolio.”

Topical steroids are the most frequently used treatment for psoriasis, but long-term use has been limited due to risks of adverse events such as epidermal atrophy.[2,3] Other local adverse reactions from topical corticosteroids may include striae, telangiectasias, hypopigmentation and contact dermatitis, and some local adverse reactions may be irreversible. 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.[1]

“Topical steroids are a cornerstone of psoriasis treatment, but the efficacy of a high-potency steroid often comes with an increased risk of adverse events and a duration of use limited to two to four weeks,” said Lawrence J. Green, M.D., associate clinical professor of Dermatology at George Washington University School of Medicine in Washington, D.C. “In clinical trials BRYHALI Lotion has demonstrated good local tolerability for up to eight weeks of treatment without sacrificing efficacy, making it an important new treatment option for psoriasis patients.”[1]

BRYHALI Lotion Clinical Data
BRYHALI Lotion was evaluated in two prospective, multicenter, randomized, double-blind clinical trials to determine its safety and efficacy. The trials were conducted in a total of 430 subjects who were 18 years of age and older with moderate to severe plaque psoriasis. In Trials 1 and 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"), compared to eight percent and 12 percent of patients treated with vehicle. There was no increase in epidermal atrophy over eight weeks of treatment.[1]

Data from both trials also 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).[1]

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]

Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression was observed and may occur with the potential for glucocorticosteroid insufficiency during or after treatment with BRYHALI Lotion.[1]

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.[4] 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.[5] Plaque psoriasis is the most common type of psoriasis.[6]

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 anti-infective products. More information can be found at www.ortho-dermatologics.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," "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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