

# Ortho Dermatologics Announces Publication Of Pivotal Phase 3 Efficacy And Safety Data On Bryhali™\* (Halobetasol Propionate) Lotion, 0.01% In The Journal Of Drugs In Dermatology

October 02, 2018

## **Two Pivotal Trials Demonstrate the Efficacy of Investigational Drug BRYHALI Lotion Over Vehicle at Eight Weeks of Treatment, with Favorable Tolerability Profile<sup>1</sup>**

LAVAL, Quebec, Oct. 2, 2018 /PRNewswire/ -- Ortho Dermatologics, one of the largest prescription dermatology health care businesses, and its parent company, Bausch Health Companies Inc. (NYSE/TSX: BHC), today announced that the *Journal of Drugs in Dermatology* has published results of two Phase 3 randomized controlled trials (Studies 1 and 2) examining the safety and efficacy of BRYHALI™\* (halobetasol propionate) Lotion, 0.01%, an investigational potent to superpotent\*\* corticosteroid, in the treatment of moderate-to-severe plaque psoriasis.<sup>1</sup> BRYHALI Lotion has a Prescription Drug User Fee Act (PDUFA) action date of October 5, 2018.

In the studies, BRYHALI Lotion was consistently more effective than vehicle in achieving treatment success, which was defined as at least a two-grade improvement from baseline in an Investigator Global Assessment (IGA) score, and 'clear' or 'almost clear' skin. By week eight, 36.5 percent (Study 1) and 38.4 percent (Study 2) of BRYHALI Lotion patients had achieved treatment success, compared to 8.1 percent and 12 percent of patients receiving vehicle. At four weeks post treatment, no rebound of symptoms was observed in patients using BRYHALI Lotion.

BRYHALI Lotion was also found to be well-tolerated, with a similar number of patients in the BRYHALI Lotion and vehicle groups reporting adverse events (21.5 percent and 23.9 percent, respectively). The most common adverse reactions ( $\geq 1\%$ ) were upper respiratory tract infection, application site dermatitis and hyperglycemia.

"Though many psoriasis patients may benefit from longer-term treatment options, that has typically not been possible with topical corticosteroids, such as halobetasol, due to concerns about adverse events," said Francisco Kerdel, M.D., Florida Academic Dermatology Center. "If approved, BRYHALI Lotion can provide physicians and their patients with a new treatment option with a longer duration of use."

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. BRYHALI Lotion was formulated containing 0.01 percent halobetasol propionate in a novel vehicle lotion and was used for up to eight weeks in the clinical trials.

"At Ortho Dermatologics, we continuously strive to better understand the evolving needs of dermatology patients and the providers who treat them each and every day, and we are accelerating our innovation to ensure our portfolio reflects those needs," said Bill Humphries, president and company group chairman, Ortho Dermatologics. "We believe these new data

demonstrate how BRYHALI may benefit many psoriasis patients, and we look forward to working with the FDA as the agency completes its review of our New Drug Application."

The U.S. Food and Drug Administration has accepted the New Drug Application for BRYHALI Lotion with a Prescription Drug User Fee Act (PDUFA) action date of October 5, 2018.

### **About the Phase 3 Studies (Study 1 and 2)**

Study 1 and Study 2 were two multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies. The studies evaluated the safety and efficacy of BRYHALI Lotion, compared to vehicle, among 430 patients 18 years or older with an IGA score of three or four, and affected BSA of three to 12 percent.

Patients were randomized 2:1 to receive BRYHALI Lotion or vehicle once-daily for eight weeks, with assessments carried out at two, four, six and eight weeks of treatment, and at a four-week post treatment follow-up visit. The primary efficacy endpoint was the percent of patients who were treatment successes at week eight (defined as those with at least a two-grade improvement from baseline in IGA score, and 'clear' or 'almost clear' skin). IGA was assessed by the investigator using a five-point scale ranging from zero (clear) to four (severe) at each study visit. Secondary efficacy data were provided at weeks two, four, six and 12. Safety and treatment emergent adverse events were evaluated throughout.

### **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.<sup>2</sup> 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.<sup>3</sup> Plaque psoriasis is the most common type of psoriasis.<sup>4</sup>

### **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 anti-infective products. More information can be found at

[www.ortho-dermatologics.com](http://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.

## References

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\* Provisional name

\*\* There are seven classes of steroids; Class 1, superpotent; Class 2, potent; Class 3, upper mid-strength, Class 4, mid-strength; Class 5, lower-mid-strength; Class 6, mild; and Class 7, least potent.

*BRYHALI is a trademark of Ortho Dermatologics' affiliated entities.*

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