BAUSCH Health

Ortho Dermatologics Announces Statistically Significant Topline Results From Second Pivotal Phase 3 Clinical Trial Evaluating IDP-126 Gel In Acne Vulgaris

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All Three Co-Primary Endpoints Were Achieved

LAVAL, QC, April 22, 2021 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") and its dermatology business, Ortho Dermatologics, one of the largest prescription dermatology health care businesses, today announced statistically significant topline results from a second pivotal Phase 3 clinical trial evaluating its investigational medicine IDP-126, a combination retinoid, anti-bacterial and antibiotic topical, to treat acne vulgaris in patients nine years of age and older. If approved, IDP-126 would be the first-in-class with this triple combination.

Acne is the most common skin problem in the United States, affecting up to 50 million Americans.[1,2]

The second Phase 3 study confirmed the findings of the first Phase 3 study, which met all of its co-primary endpoints. This second Phase 3 study achieved all three co-primary endpoints at week 12 with statistical significance, including:

- Absolute change from baseline in inflammatory lesion count [p-value<0.001]
- Absolute change from baseline in non-inflammatory lesion count [p-value<0.001]
- Percentage of patients who achieved treatment success (defined as a two-grade reduction from baseline and 'clear' or 'almost clear' skin in Evaluator's Global Severity Score (EGSS)) (p=0.001)

Treatment success was 50.5% and 20.5% for IDP-126 and its vehicle, respectively. The data also demonstrated a benefit for patients as early as two weeks.

"The results from this pivotal Phase 3 trial indicate a strong safety, tolerability and efficacy profile for IDP-126 and reinforce its potential as a first-in-class treatment option for millions of patients struggling with acne," said Scott Hirsch, president, Ortho Dermatologics, and senior vice president and chief strategy officer, Bausch Health. "Following the results of a comparative bridging study, we hope to submit a New Drug Application for IDP-126 to the U.S. Food and Drug Administration in the second half of 2022."

"The positive results of this second Phase 3 study for IDP-126 are consistent with the strong, conclusive results seen in the findings from the first Phase 3 study. If approved, IDP-126 will deliver a triple-combination retinoid therapy – three active ingredients into one product – which could have a meaningful impact for my patients suffering from acne," said Linda Stein Gold, M.D., director, Dermatology Clinical Research, Henry Ford Health System.

Summary of Second Phase 3 Study Results
The multicenter, randomized, double-blind, vehicle-controlled, 12-week study was designed to

assess the safety, tolerability and efficacy of IDP-126 Gel in comparison to IDP-126 vehicle gel. The data was based on results from 193 participants nine years of age and older who were randomized to either receive treatment with IDP-126 gel applied topically to the face once daily for 12 weeks or administration of placebo (IDP-126 vehicle gel) applied topically to the face once daily for 12 weeks. The study was conducted at 13 locations in the United States. Treatment emergent adverse events (TEAE) reported in >2% of patients included application site pain, dryness, irritation, erythema, exfoliation and xerosis.

About Ortho Dermatologics

Ortho Dermatologics is one of the largest 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 is further complemented by Solta Medical, the maker of Fraxel®, Thermage®, Clear + Brilliant® and Vaser® ultrasonic assisted liposuction for aesthetic applications. 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 www.bauschhealth.com

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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," "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, 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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