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ORTHO DERMATOLOGICS ANNOUNCES STATISTICALLY SIGNIFICANT TOPLINE RESULTS FROM SECOND PIVOTAL PHASE 3 CLINICAL TRIAL EVALUATING IDP-126 GEL IN ACNE VULGARIS

All Three Co-Primary Endpoints Were Achieved

RALEIGH, N.C., April 27, 2021 – 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 using EGSS 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.

“Most acne patients are treated with a regimen that includes several different classes of medicine because of the complicated nature of the disease. This approach can be cumbersome for patients and exacerbate poor adherence rates, which are already low for acne patients when using simple regimens,” said Scott Hirsch, president, Ortho Dermatologics, and senior vice president and chief strategy officer, Bausch Health. “Dermatologists have been asking for a triple combination therapy to help them combat this issue for decades. Ortho Dermatologics has achieved a technological breakthrough with IDP-126 to deliver on this need, which, if approved, will provide the first and only triple combination treatment option to help patients struggling with acne.”

“The impressive results of this second Phase 3 study for IDP-126 are consistent with the results seen in the findings from the first Phase 3 study, particularly the strong efficacy results. I am encouraged that, if approved, IDP-126 will deliver a triple-combination therapy – three active ingredients in one product – which could simplify the treatment regimen and have a meaningful impact on my patients suffering from acne,” said Linda Stein Gold, M.D., director, Dermatology Clinical Research, Henry Ford Health System.

Following the results of a comparative bridging study, Ortho Dermatologics expects to submit a New Drug Application for IDP-126 to the U.S. Food and Drug Administration in the second half of 2022.

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 prescription and aesthetic 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 also includes several leading medical device systems for aesthetic applications, such as skin tightening and resurfacing, laser hair removal and preventative therapeutic skin care treatments. 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,” “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

1. American Academy of Dermatology. (2020). Skin conditions by the numbers. Retrieved from <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. Accessed April 20, 2021.
2. Mayo Clinic. (2020). Acne. Retrieved from <https://www.mayoclinic.org/diseases-conditions/acne/symptoms-causes/syc-20368047>. Accessed April 20, 2021.

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