BAUSCH Health

Ortho Dermatologics Announces U.S. Food and Drug Administration New Drug Application Filing Acceptance for Investigational Acne Treatment IDP-126 Gel

May 01, 2023

PDUFA Action Date is October 20, 2023

LAVAL, Quebec, May 1, 2023 – Bausch Health Companies Inc. (NYSE/TSX: BHC) and its dermatology business, Ortho Dermatologics, today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for investigational IDP-126 (clindamycin 1.2%/adapalene 0.15%/benzoyl peroxide 3.1%) Gel with a Prescription Drug User Fee Act (PDUFA) action date of October 20, 2023. If approved, IDP-126 has the potential to be the first of its kind fixed dose triple combination treatment for acne vulgaris.

"In requesting approval from the FDA, we are hopeful that we may be able to bring a first-of-its kind triple-combination acne treatment to the millions of Americans who suffer from acne each year," said Thomas J. Appio, Chief Executive Officer, Bausch Health. "The treatment of acne can be challenging and may often require multiple therapies. With the potential of a triple-combination product, we believe IDP-126, if approved, could not only help alleviate the existing burden of treatment but also potentially help patient outcomes."

The NDA submitted for IDP-126 includes data from two successfully completed Phase 3 multicenter, randomized, placebo controlled clinical trials in 363 patients with acne vulgaris. Both studies met all co-primary efficacy endpoints, including absolute change from baseline in inflammatory lesion count, absolute change from baseline in non-inflammatory lesion count and percentage of patients achieving treatment success (2 grade reduction of the EGSS with a final score of clear (0) or almost clear (1)). Both studies showed treatment-emergent adverse events were of mild to moderate severity.

Acne is the most common skin problem in the United States, which occurs when hair follicles become obstructed with sebum and skin cells, resulting in the formation of whiteheads, blackheads, or pimples to appear on the face, forehead, chest, upper back and shoulders.[1,2] Up to 50 million Americans have acne.2 Depending on its severity, acne can cause emotional distress and scar the skin.[2]

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 conditions, including psoriasis, onychomycosis, actinic keratosis, acne, atopic dermatitis and other dermatoses. 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 diversified pharmaceutical company

whose mission is to improve people's lives with our healthcare products. We develop, manufacture and market a range of products primarily in gastroenterology, hepatology, neurology, dermatology, international pharmaceuticals and eye health, through our controlling ownership interest in Bausch + Lomb Corporation. With our leading durable brands, we are delivering on our commitments as we build an innovative company dedicated to advancing global health. For more information, visit
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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," "hopes," "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, launches 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

- 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 March 13, 2023.
- Mayo Clinic. (2020). Acne. Retrieved from https://www.mayoclinic.org/diseasesconditions/acne/symptoms-causes/syc-20368047. Accessed March 13, 2023.

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