BAUSCH Health

CABTREO™ (clindamycin phosphate, adapalene and benzoyl peroxide) Topical Gel for the Treatment of Acne Vulgaris Now Available in the U.S.

January 30, 2024

LAVAL, Quebec, Jan. 30, 2024 -- Bausch Health Companies Inc. (NYSE/TSX: BHC) and its dermatology business, Ortho Dermatologics, today announced the U.S. launch of CABTREO™ (clindamycin, adapalene, benzoyl peroxide) Topical Gel, 1.2%/0.15%/3.1% indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

"With today's launch of CABTREO, millions of Americans who suffer from acne each year have access to a new once-daily triple-combination topical acne treatment," Thomas J. Appio, Chief Executive Officer, said. "In many instances, acne treatment requires using multiple products and dosing regimens, which can pose a number of challenges for patients. CABTREO has the potential to simplify dosing with a once daily topical acne treatment regimen."

CABTREO Topical Gel is the first and only U.S. Food and Drug Administration-approved fixed-dose, once- daily triple-combination topical treatment for acne and offers three mechanisms of action, combining an antibiotic, retinoid and antibacterial, to provide a proven, safe and effective treatment.

The FDA approved CABTREO Topical Gel on Oct. 20, 2023, based on data from two multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies that demonstrated CABTREO Topical Gel resulted in statistically significant reductions in both inflammatory and non-inflammatory lesions compared to vehicle. At week 12, 50.0% of participants achieved treatment success with CABTREO versus 22.6% with vehicle gel (P<0.001). CABTREO resulted in >70% reductions in inflammatory and noninflammatory lesions at week 12 (77.9%% and 73.0%, respectively), which were significantly greater than vehicle (57.9% and 48.2%; P<0.001, both).

The most common adverse reactions (occurring in >1% of the CABTREO group and greater than the vehicle group) were application site reactions, pain, erythema, dryness, irritation, exfoliation, and dermatitis.

About Acne Vulgaris

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 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]

What is CABTREO?

CABTREO (clindamycin phosphate, adapalene and benzoyl peroxide) Topical Gel 1.2%/0.15%/3.1% is a prescription medicine used on the skin only (topical use) to treat acne

vulgaris in adults and children 12 years of age and older. Do not use CABTREO in your mouth, eyes, or vagina.

IMPORTANT SAFETY INFORMATION

Do not use CABTREO if you have had an allergic reaction to clindamycin, adapalene, benzoyl peroxide, lincomycin, or any of the ingredients in CABTREO or have Crohn's disease, ulcerative colitis, inflammation of the colon (colitis), or severe diarrhea with antibiotic use.

Before using CABTREO, tell your healthcare provider about all your medical conditions, including if you: plan to have surgery, are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed, have other skin problems, including cuts, abrasions, sunburn, or eczema; or use other skin and topical acne products that may increase the irritation of your skin when used with CABTREO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the- counter medicines, vitamins, herbal supplements, and if you take or use a medicine that contains erythromycin. CABTREO should not be used with products that contain erythromycin.

What should I avoid while using CABTREO?

- Avoid or limit your time in sunlight, including use of sunlamps or tanning beds during treatment with CABTREO as it can make you more sensitive, and you could get severe sunburn. Use sunscreen and wear clothes including a hat that covers the treated areas of your skin if you have to be in sunlight.
- Cold weather and wind may irritate skin treated with CABTREO.
- Avoid applying CABTREO to areas with skin problems including, cuts, abrasions, sunburned skin, or eczema.
- Avoid skin products that may dry or irritate your skin.
- Avoid the use of "waxing" as a hair removal method on skin treated with CABTREO.

What are the possible serious and most common side effects of CABTREO?

Tell your doctor right away if you experience side effects, including:

- **Allergic reactions:** Stop using CABTREO if you have hives, rash, severe itching, swelling of your face, eyes, lips, tongue or throat, trouble breathing, throat tightness, feeling faint, dizzy, or lightheaded.
- **Inflammation of the colon (colitis):** Stop using CABTREO if you have severe stomach (abdominal) cramps, watery diarrhea, or bloody diarrhea during treatment, and within several weeks after treatment with CABTREO.
- **Sensitivity to sunlight. See "What should I avoid while using CABTREO".**
- **Skin irritation** at the application site is common with CABTREO and may include redness, scaling, dryness, stinging, burning, itching, and swelling.

These are not all the possible side effects of CABTREO. Call your doctor for medical advice about side effects. You may report side effects to Bausch Health US, LLC at 1-800-321-4576 or FDA at 1-800-FDA- 1088 or
www.fda.gov/medwatch

Please click
here
for full Prescribing Information, Patient Information and Instructions for Use.

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
https://www.ortho-dermatologics.com.

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 health care 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. 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
www.bauschhealth.com
and connect with us on
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Forward-Looking Statements

This news release may contain forward-looking statements about the future performance of Bausch Health which may generally be identified by the use of the words "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "subject to" 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. Actual results are subject to other risks and uncertainties that relate more broadly to Bausch Health's overall business, including those more fully described 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.

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 March13, 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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Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
848-264-0934

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