Sun Pharmaceutical Industries Limited
SUN HOUSE, CTS No. 201 B/1,
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Tel.: (91-22) 4324 4324 Fax.: (91-22) 4324 4343
CIN: L24230GJ1993PLC019050
www.sunpharma.com

November 01, 2021

National Stock Exchange of India Limited,
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra Kurla Complex,
Bandra (East), Mumbai- 400 051

Scrip Symbol: SUNPHARMA

BSE Limited,
Market Operations Dept.
P. J. Towers,
Dalal Street,
Mumbai - 400 001

Scrip Code: 524715

Sub: Press Release

Dear Sir / Madam,

Please find enclosed herewith our Press Release relating to announcement of WINLEVI's availability in US, which we shall be releasing after sending this letter to you.

This is for your information and dissemination.

Thanking you,

Yours faithfully,
For **Sun Pharmaceutical Industries Limited**

A. I. Bhuta

Ashok I. Bhuta
Compliance Officer
Enclosed: As above

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Sun Pharma Announces Availability of WINLEVI® (clascoterone) cream 1% in the U.S. for Topical Treatment of Acne Vulgaris

- ***First-in-class androgen receptor inhibitor enables use in both males and females***
- ***First FDA-approved novel topical mechanism for acne in nearly 40 years***

MUMBAI, India and PRINCETON, N.J., November 1, 2021 – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP.IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) today announced the availability of WINLEVI (clascoterone) cream 1% in the United States (U.S). A first-in-class topical androgen receptor inhibitor, WINLEVI was approved by the U.S. Food and Drug Administration (FDA) in August 2020 for the topical treatment of acne vulgaris in patients 12 years of age and older.

WINLEVI is the first FDA-approved acne drug with a first-in-class mechanism of action in nearly 40 years.[1,2] It works by inhibiting the effects of androgen receptors in cells of the sebaceous glands (oil-producing glands in the skin) to help reduce sebum (oil) production and inflammation.[3,4] It is suitable for use in both males and females.[1,3]

"The U.S. launch of WINLEVI enhances Sun Pharma's specialty product portfolio and reflects our commitment to meeting patients' needs by providing innovative dermatology medicines," said Abhay Gandhi, CEO, North America of Sun Pharma. "With its safety and tolerability profile, combined with its demonstrated efficacy in clinical trials, WINLEVI has the potential to be an important topical treatment option for the millions of Americans affected by acne vulgaris."

The most common adverse reactions occurring in 7% to 12% of patients receiving WINLEVI in two clinical trials are, erythema (reddening), pruritus (itching), and scaling/dryness. Additionally, edema, stinging, and burning occurred in at least 3% of patients and were reported in a similar percentage of participants treated with vehicle.[3]

The most prevalent skin condition in the U.S., acne affects up to 50 million Americans annually.[5] Prior to the availability of WINLEVI, conventional topical approaches to acne treatment focused on either addressing follicular hyperkeratinization, reducing inflammation, or exerting antibacterial effects.[6-8] While such approaches are all key to managing acne, to date, none of the currently available topical therapies for acne has focused on inhibiting sebum production resulting from androgen stimulation in sebaceous gland cells.

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"Androgen receptor inhibition has long been the missing link in the topical management of acne vulgaris," noted Julie Harper, MD, founding director and past president of the American Acne and Rosacea Society. "Androgens are the most important hormone in regulating sebum production – which is a major cause of acne in both males and females – yet WINLEVI is the first FDA-approved topical therapy to address this and does so without inducing the systemic side effects associated with oral androgen receptor inhibitors. The availability of WINLEVI is thus a welcome acne treatment option."

Please visit www.winlevi.com for more information on WINLEVI, or www.sunpharmaderm.com to learn more about Sun Pharma's medical dermatology portfolio.

About WINLEVI® (clascoterone) cream 1%

WINLEVI is approved for the topical treatment of acne vulgaris in people aged 12 and older. Although the exact mechanism of action for WINLEVI is unknown, laboratory studies suggest the active ingredient, clascoterone, competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles.[2]

Androgens are widely recognized as the most important of all hormones in terms of regulating sebum production.[9] Within the skin, androgens bind to androgen receptors, causing increased sebum production and inflammation.[4] In particular, the skin of patients with acne vulgaris produces higher levels of the androgens testosterone and dihydrotestosterone (DHT) than the skin of healthy individuals.[6] Current oral hormonal therapies have been shown to be effective in treating acne regardless of whether androgen levels are elevated.[9] However, whereas certain oral hormonal therapies are recommended for use in some female patients with acne, their use in males has been limited due to the potential risk of systemic side effects such as gynecomastia (overdevelopment or enlargement of breast tissue) and the inability to grow a beard.[1,9]

WINLEVI binds to the androgen receptor competing with androgens such as DHT on cells within the sebaceous gland. Although its precise mechanism of action is unknown, studies suggest WINLEVI inhibits androgen receptors in the skin and reduces production of sebum and inflammation.[3,4]

Additionally, WINLEVI is rapidly metabolized in the skin, limiting systemic absorption.[12,13] That property appears to contribute to its well-tolerated safety profile in both men and women.

In clinical studies, a 12-week course of WINLEVI therapy was associated with significant reductions in both inflammatory and noninflammatory lesions, as well as a significant increase in the investigator's global assessment (IGA) of treatment success (defined as at least a 2-point reduction in IGA score from baseline and an IGA score of 0 [clear] or 1 [almost clear], compared to vehicle) (P<0.0001 for all measurements).[3]

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In two Phase 3 clinical studies over 12 weeks, few systemic adverse events were observed in less than 2% of patients. Most local skin reactions (LSRs) were trace or mild in severity. The most frequently reported LSRs were erythema (redness) and scaling/dryness.[3] Among the 11.1% of participants who experienced treatment-emergent adverse events (TEAEs) in a phase 3, open-label, nine-month extension safety study, 75.9% of these events were mild, 24.1% were moderate, and none were severe.[1,14]

WINLEVI is supplied in a 60-gram epoxy-lined aluminum tube. Each gram of WINLEVI contains 10 mg of clascoterone in a white to almost white cream. Patients are instructed to cleanse the affected area gently, and after the skin is dry, to apply a uniform layer of WINLEVI twice per day, in the morning and the evening.[3]

Complete prescribing information is available at www.winlevi.com.

INDICATION
WINLEVI® (clascoterone) cream 1% is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:
None.

WARNINGS AND PRECAUTIONS
Local Irritation: Pruritus, burning, skin redness or peeling may be experienced with WINLEVI cream. If these effects occur, discontinue or reduce the frequency of application of WINLEVI cream.
Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with WILEVI In the PK trial, HPA axis suppression was observed in 1/20 (5%) of adult subjects and 2/22 (9%) of adolescent subjects at Day 14. All subjects returned to normal HPA axis function at follow-up 4 weeks after stopping treatment. Conditions which augment systemic absorption include use over large surface areas, prolonged use, and the use of occlusive dressings. Attempt to withdraw use if HPA axis suppression develops.

Pediatric patients may be more susceptible to systemic toxicity.

Hyperkalemia: Elevated potassium levels were observed in some subjects during the clinical trials. Shifts from normal to elevated potassium levels were observed in 5% of WINLEVI-treated subjects and 4% of vehicle-treated subjects.

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ADVERSE REACTIONS

Most common adverse reactions occurring in 7 to 12% of patients are erythema/reddening, pruritus and scaling/dryness. Additionally, edema, stinging, and burning occurred in >3% of patients and were reported in a similar percentage of subjects treated with vehicle.

References:

1. Hebert A, Thiboutot D, Stein Gold L, et al. Efficacy and safety of topical clascoterone cream, 1%, for treatment in patients with facial acne: two phase 3 randomized clinical trials. *JAMA Dermatol.* 2020;156(6):621-630.
2. Leyden JJ, Del Rosso JQ, Baum EW. The use of isotretinoin in the treatment of acne vulgaris: clinical considerations and future directions. *J Clin Aesthet Dermatol.* 2014;7(2 Suppl): S3-S21.
3. WINLEVI® (clascoterone) cream 1% prescribing information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; September 2021.
4. Rosette C, Agan FJ, Mazzetti A, Moro L, Gerloni M. Cortexolone 17α-propionate (clascoterone) is a novel androgen receptor antagonist that inhibits production of lipids and inflammatory cytokines from sebocytes in vitro. *J Drugs Dermatol.* 2019;18(5):412-418.
5. Skin conditions by the numbers. American Academy of Dermatology Association, 2021. Available at Skin conditions by the numbers (aad.org). Accessed September 15, 2021.
6. Del Rosso JQ, Kircik LH, Stein Gold L, et al. Androgens, androgen receptors, and the skin: from the laboratory to the clinic with emphasis on clinical and therapeutic implications. *J Drugs Dermatol.* 2020;19(3):30-35.
7. Chien A. Retinoids in acne management: review of current understanding, future considerations, and focus on topical treatments. *J Drugs Dermatol.* 2018;17(12):S51-S55.
8. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol.* 2016;74(5):945-973.e33.
9. Elsaie ML. Hormonal treatment of acne vulgaris: an update. *Clin Cosmet Investig Dermatol.* 2016;9:241-248.
10. Chen WC, Thiboutot D, Zoubulis CC. Cutaneous androgen metabolism: basic research and clinical perspectives. *J Invest Dermatol*. 2002;119:992-1007.
11. Iftikhar U, Choudhry N. Serum levels of androgens in acne and their role in acne severity. *Pak J Med Sci.* 2019;35(1):146-150.
12. Mazzetti A, Moro L, Gerloni M, Cartwright M. A phase 2b, randomized, double-blind vehicle controlled, dose escalation study evaluating clascoterone 0.1%, 0.5%, and 1% topical cream in subjects with facial acne. *J Drugs Dermatol*. 2019;18(6):570.
13. Ferraboschi P, Legnani L, Giuseppe C, Moro L, Ragonesi L, Colombo D. A full conformational characterization of antiandrogen cortexolone- 17α-propionate and related compounds through theoretical calculations and nuclear magnetic resonance spectroscopy. *Med Chem Commun.* 2014;5:904-914.
14. Data on file. Sun Pharmaceuticals Industries, Inc.; August 2021.

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About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across six continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 6-7% of annual revenues in R&D. For further information, please visit www.sunpharma.com and follow us on Twitter @SunPharma_Live.

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