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Sun Pharma Presents Phase 3 Data for WINLEVI® (clascoterone) cream 1% for the Topical Treatment of Acne Vulgaris at the AAD Annual Meeting

- *Results from two pivotal clinical trials showed favorable safety and efficacy data for WINLEVI in patients with acne aged 12 years and older*
- *Data supports therapeutic rationale for first-in-class androgen receptor inhibitor*

MUMBAI, India and PRINCETON, N.J., March 25, 2022 – 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 that the Company's wholly owned U.S. subsidiary presented data from two pivotal Phase 3 clinical trials of WINLEVI (clascoterone) cream 1% for the topical treatment of acne vulgaris (acne). The results, which showed favorable safety and efficacy data in patients 12 years of age and older with acne, were reported today in a poster podium presentation at the American Academy of Dermatology (AAD) 2022 Annual Meeting in Boston, Massachusetts.

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] Although its exact mechanism of action is unknown, laboratory studies suggest that WINLEVI 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] It is suitable for use in both males and females.[1]

"The data presented at AAD 2022 add to the growing body of evidence supporting the use of WINLEVI as a foundational acne treatment," said Nicholas Squittieri, MD, Associate Vice President of Medical Affairs at Sun Pharma, and co-author of the AAD poster presentation. "We look forward to further exploring its clinical utility as we conduct more studies and data analyses."

"Before WINLEVI became available, there was no topical medication available that was able to reduce sebum production, which is a major cause of acne," commented Hilary Baldwin, MD, Medical Director of the Acne Treatment and Research Center in Brooklyn, NY, and past president of the American Acne and Rosacea Society (AARS). "It is therefore encouraging to see favorable efficacy and safety data results from the latest analysis of the WINLEVI Phase 3 clinical trials. This data should also provide dermatologists with confidence that they can use WINLEVI to treat both females and males with acne."

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The two multicenter, randomized, double-blind pivotal Phase 3 trials enrolled more than 1440 subjects with moderate-to-severe acne vulgaris who received either WINLEVI or placebo for 12 weeks. The primary efficacy endpoints were 1) the proportion of patients achieving "success," defined as an Investigator Global Assessment (IGA) score of 0 ("clear") or 1 ("almost clear"), with at least a 2-point reduction in IGA score from baseline; and 2) absolute change from baseline in non-inflammatory lesion counts (NILC) and inflammatory lesion counts (ILC) at Week 12. Safety was assessed from local skin reactions (LSRs) and treatment-emergent adverse events (TEAEs) through Week 12 (measured at baseline and at Weeks 4, 8, and 12).

In the two studies, 18.8% and 20.9% of WINLEVI-treated patients achieved success based on IGA at Week 12, compared with 8.7% and 6.6% of patients receiving placebo ($P < 0.01$). The mean absolute change from baseline in NILCs at Week 12 was -20.4 and -19.5 for patients treated with WINLEVI, versus -13.0 and -10.8 for placebo-treated patients ($P \leq 0.0001$). The mean absolute change from baseline in ILCs at Week 12 was -19.3 and -20.1 in the WINLEVI groups, compared to -15.4 and -12.6 in the two studies' placebo groups ($P < 0.01$).

The safety profile of WINLEVI was similar to that of placebo in the two studies. TEAEs occurred in 38 (11.1%) and 41 (11.2%) of WINLEVI-treated patients and in 41 (11.7%) and 50 (13.8%) of those who received placebo. No severe or serious TEAEs occurred in any patient treated with WINLEVI. The most frequently reported TEAEs were nasophyaryngitis (1.8% and 3.7% for WINLEVI, 1.1% and 1.9% for placebo), headache (0.6% and 0.3% for WINLEVI, 1.1% and 0.8% for placebo), and oropharyngeal pain (0.6% and 0.3% for WINLEVI, 1.1% and 1.1% in both placebo arms). In both studies, the frequencies of each LSR were similar between treatment groups, and the majority of patients did not experience each reaction. The most frequent LSRs were erythema (redness) and scaling/dryness, with the majority of reactions characterized as minimal or mild.

Acne is the most prevalent skin condition in the U.S., affecting up to 50 million Americans annually.[4] Prior to the availability of WINLEVI, conventional topical approaches to acne treatment focused on either addressing follicular hyperkeratinization, reducing inflammation, or exerting antibacterial effects.[5,6]

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

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] WINLEVI is rapidly metabolized in the

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skin, limiting systemic absorption. That property appears to contribute to its well-tolerated safety profile in both men and women.

Androgens are widely recognized as the most important of all hormones in terms of regulating sebum production.[7] Within the skin, androgens bind to androgen receptors, causing increased sebum production and inflammation.[3] In particular, the skin of patients with acne vulgaris produces higher levels of the androgens testosterone and DHT than the skin of healthy individuals.[8] Current oral hormonal therapies have been shown to be effective in treating acne regardless of whether androgen levels are elevated.[7] 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.[1,7]

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.[9]

For complete prescribing information please click here.

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.

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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.

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.

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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% 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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