

FOR IMMEDIATE RELEASE

Sun Pharma Canada Launches ^{PR}WINLEVI® (clascoterone cream 1% w/w), a Novel Topical Treatment for Acne

- WINLEVI (clascoterone cream 1% w/w) for male and female acne patients 12 years of age and older is now available in Canada.
- WINLEVI is the first and only topical androgen receptor inhibitor, and the newest Health Canada-approved formulation to target the hormonal component of acne in 40 years.

MUMBAI, INDIA and BRAMPTON, ON, CANADA, September 27, 2023 - Sun Pharma Canada Inc., a wholly owned subsidiary of Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, “Sun Pharma”) is pleased to announce that ^{PR}WINLEVI (clascoterone cream 1% w/w) is now available in Canada. WINLEVI is the first and only androgen receptor inhibitor indicated for the topical treatment of acne vulgaris (acne) in patients 12 years of age and older.

WINLEVI works differently from any other topical acne treatment. Instead of a topical approach to acne treatment that focuses on follicular hyperkeratinization, reducing inflammation or exerting antibacterial effects, WINLEVI is thought to reduce the effects of acne hormones on skin by disrupting the androgen cascade. While the exact way that WINLEVI works is unknown, it aims to inhibit the effects of androgen receptors in cells of the sebaceous glands (oil-producing glands in the skin) to help reduce sebum (oil) production and inflammatory cytokines.^{1,2}

“Sun Pharma is excited to launch this much-anticipated, innovative topical solution for the millions of Canadians affected by acne,” said Abhay Gandhi, North America CEO of Sun Pharma. “The launch of WINLEVI enhances Sun Pharma’s specialty product portfolio in Canada and reflects our commitment to providing innovative dermatology medicines that address patients’ needs.”

Despite data showing that acne affects approximately 20 per cent of Canadians³ and can affect patients’ health-related quality of life through potentially increased risk of depression and anxiety,^{4, 5, 6} innovation in the space is minimal. WINLEVI is the first and only topical androgen receptor inhibitor, and the newest Health Canada-approved formulation to target the hormonal component of acne in 40 years.¹

“Since Health Canada’s approval of WINLEVI, there has been much excitement among dermatologists related to this novel therapeutic and its ability to address an unmet need of Canadians with acne – it’s an opportunity to help improve the quality of life of our patients,” said Dr. Sonya Abdulla, a board-certified dermatologist at Dermatology on Bloor.

For more information about WINLEVI, ask your physician, visit www.sunpharma.com/canada or call 1-833-388-0532.

About ^{PR}WINLEVI (clascoterone cream 1% w/w)

WINLEVI is approved for the topical treatment of acne vulgaris in people 12 years of age 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.⁷

Androgens are widely recognized as the most important of all hormones in terms of regulating sebum production.⁸ Within the skin, androgens bind to androgen receptors, causing increased sebum production and inflammation.⁹ In particular, the skin of

Sun Pharmaceutical Industries Ltd.

SUN HOUSE, CTS No. 201 B/1,
Western Express Highway, Goregaon (E),
Mumbai 400063, India
Tel.: (91-22) 4324 4324 Fax.: (91-22) 4324 4343
CIN: L24230GJ1993PLC019050
www.sunpharma.com



patients with acne vulgaris produces higher levels of the androgens testosterone and dihydrotestosterone (DHT) than the skin of healthy individuals.¹⁰ Current oral hormonal therapies have been shown to be effective in treating acne regardless of whether androgen levels are elevated.⁸ 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, 8}

Additionally, WINLEVI is rapidly metabolized in the skin, limiting systemic absorption.^{11, 12}

In clinical studies, a 12-week course of WINLEVI therapy was associated with significant reductions in both inflammatory and non-inflammatory lesions, as well as a significant increase in the number of patients achieving treatment success when compared to vehicle.²

In two Phase 3 clinical studies, 18.8% and 20.9% of WINLEVI-treated patients achieved success based on their Investigator's Global Assessment (IGA) scores at Week 12, compared with 8.7% and 6.6% of patients receiving vehicle ($P < 0.001$). The mean absolute change from baseline in non-inflammatory lesion counts (NILCs) at Week 12 was -20.4 and -19.5 for patients treated with WINLEVI, versus -13.0 and -10.8 for vehicle-treated patients ($P < 0.001$). The mean absolute change from baseline in inflammatory lesion counts (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' vehicle groups ($P < 0.01$).²

There were no adverse events reported as an adverse drug reaction in $> 1\%$ of patients. Most local skin reactions (LSRs) were trace or mild in severity and occurred in a similar percentage of patients treated with vehicle. The most frequently reported LSRs were erythema (redness) and scaling/dryness.²

WINLEVI is supplied in 30 gram aluminum tubes. 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 thin even layer of WINLEVI over the area prone to acne, twice a day, in the morning and in the evening.

About Sun Pharma Canada Inc.

Sun Pharmaceutical Industries Limited is growing its presence in Canada, bringing together the power of a global network with localized research and care to address the unmet needs of Canadian patients and healthcare providers.

Sun Pharma Canada Inc., a wholly owned subsidiary of Sun Pharmaceutical Industries Limited, is focused on providing innovative medicines in dermatology and ophthalmology, bringing greater access and support for patients.

Patients and healthcare providers are at the centre of everything and Sun Pharma's "passion is clear". Sun Pharma's commitment to listening, acting and caring means the team is able to respond to distinct needs and provide personalized care, while addressing important gaps in treatment and quality of life.

Sun Pharma offers a wide range of affordable medicines for the Canadian population. Together with Taro Pharmaceutical Industries Ltd. (a subsidiary of Sun Pharma) these complementary companies bring together capabilities in specialty and niche segments coupled with a presence in the top 15 Canadian generic products.

About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's fourth largest specialty generics company with presence in Specialty, Generics and Consumer Healthcare products. It is the largest pharmaceutical company in India, and is a leading generic company in the US as well as Global Emerging Markets. Sun's high growth Global Specialty portfolio spans innovative products in dermatology, ophthalmology, onco-dermatology and accounts for over 16% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multi-cultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on Twitter @SunPharma_Live.

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. ^{PR}WINLEVI® (clascoterone cream 1% w/w, Topical Anti-Androgen) Product Monograph Including Patient Medication Information. Sun Pharmaceutical Industries Limited.; June 15, 2023
3. (n.d.). *About Acne, What is Acne?* Acne and Rosacea Society of Canada. Retrieved May 10, 2023, from <https://www.acneaction.ca/about-acne/about-acne/>
4. Vallerand IA, Lewinson RT, Parsons LM et al. Risk of depression among patients with acne in the U.K.: a population-based cohort study. *British Journal of Dermatology* 2018;178(3):e194–e195.
5. Samuels DV, Rosenthal R, Lin R, Chaudhari S, Natsuaki MN. Acne vulgaris and risk of depression and anxiety: A meta-analytic review. *Journal of the American Academy of Dermatology* 2020;83(2):532– 541.
6. Halvorsen JA, Stern RS, Dalgard F, Thoresen M, Bjertness E, Lien L. Suicidal ideation, mental health problems, and social impairment are increased in adolescents with acne: a population-based study. *Journal of Investigative Dermatology* 2011;131(2):363–370.
7. 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.
8. Elsaie ML. Hormonal treatment of acne vulgaris: an update. *Clin Cosmet Investig Dermatol.* 2016;9:241-248.
9. Rosette C, Agan FJ, Mazzetti A, Moro L, Gerloni M. Cortexolone 17 α -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.
10. 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.
11. 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.
12. Ferraboschi P, Legnani L, Giuseppe C, Moro L, Ragonesi L, Colombo D. A full conformational characterization of antiandrogen cortexolone- 17 α -propionate and related compounds through theoretical calculations and nuclear magnetic resonance spectroscopy. *Med Chem Commun.* 2014;5:904-914.

Disclaimer:

Statements in this "Document" describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied. The Company undertakes no obligation to update or revise forward looking statements to reflect developments or circumstances that arise or to reflect the occurrence of unanticipated developments/circumstances after the date hereof.

SOURCE Sun Pharma Canada Inc.

Investors

Dr. Abhishek Sharma
Tel +91 22 4324 4324, Xtn 2929
Tel (D) +91 22 4324 2929
Mobile +91 98196 86016
E mail abhi.sharma@sunpharma.com

Media

Gaurav Chugh
Tel +91 22 4324 4324, Xtn 5373
Tel (D) +91 22 4324 5373
Mobile +91 98104 71414
E mail gaurav.chugh@sunpharma.com

Canadian Media

Janet Metz
Mobile +1 609-389-3044
E mail janet.metz@sunpharma.com