

Sun Pharmaceutical Industries Limited

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



26 July 2022.

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

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

Scrip Symbol: SUNPHARMA

Scrip Code: 524715

Sub: Press Release

Dear Sir / Madam,

Please find enclosed herewith our Press Release relating to territory expansion of license and supply agreement between Sun Pharma and Cosmo for WINLEVI[®], 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**

(Anoop Deshpande)
Company Secretary and Compliance Officer

Encl: as above



FOR IMMEDIATE RELEASE

Sun Pharma and Cosmo Announce Territory Expansion of License and Supply Agreements for WINLEVI® to include Japan, Australia, New Zealand, Brazil, Mexico and Russia

Mumbai, India and Dublin, Ireland, July 26, 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) and Cassiopea, a subsidiary of Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) ("Cosmo") today announced the signing of addendums to the License and Supply Agreements for WINLEVI (clascoterone) cream 1% expanding the territory to include Japan, Australia, New Zealand, Brazil, Mexico and Russia. In 2021, Sun Pharma and Cassiopea had signed License and Supply Agreements for the United States and Canada markets. Sun Pharma launched WINLEVI in the US market in November 2021.

Under the terms of the above referred agreements, Sun Pharma will receive from Cassiopea the exclusive right to develop and commercialize WINLEVI in Japan, Australia, New Zealand, Brazil, Mexico and Russia. Cosmo will be the exclusive supplier of the product. Cassiopea will receive an upfront payment of US\$ 7 million, potential regulatory and sales milestones and customary double-digit royalties on net sales.

Aalok Shanghvi, EVP & Head - Generic R&D, Generic Global BD and Emerging Markets, Sun Pharma said, "WINLEVI is a new class of topical medication and it continues to generate significant interest amongst dermatologists in the US. The expansion of our agreement with Cosmo will enable us to make this new acne treatment available to patients in many more countries and is in line with our strategy to build a global portfolio of specialty products."

Diana Harbort, President of Cosmo Dermatology Division, said: "We are very pleased to expand our agreement with Sun Pharma making WINLEVI available to more patients around the world. Sun Pharma's early success with WINLEVI in the US makes us highly confident of their ability to maximize the opportunity in the expanded territory."

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. 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 WINLEVI is the first FDA-approved acne drug with a first-in-class mechanism of action in nearly 40 years.^{1,2}

® - All brand names and trademarks are the property of their respective owners.

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.



About Cosmo

Cosmo is a pharmaceutical company focused on developing and commercialising products to treat selected gastrointestinal disorders, to improve endoscopy quality measures through aiding the detection of colonic lesions and to treat selected dermatological conditions. Cosmo develops and manufactures products which are distributed globally by selected partners including Lialda[®] (mesalamine) delayed release tablets, Uceris[®]/Cortiment[®] (budesonide) extended release tablets and WINLEVI. Cosmo has also developed medical devices for endoscopy and has a partnership with Medtronic for the global distribution of GI Genius[™] which uses artificial intelligence to help detect potential signs of colon cancer. Cosmo has licensed Aemcolo[®] (rifamycin) delayed-release tablets to Red Hill Biopharma Ltd. for the US and has licensed Relafalk[®] (rifamycin) to Dr. Falk GmbH for the EU and other countries. The company also has a rich development pipeline. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

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.

About WINLEVI[®] (clascoterone) cream 1%

WINLEVI is approved in the U.S. 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 skin, limiting systemic absorption. Most common adverse reactions include erythema/reddening, pruritus, and scaling/dryness.

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 an 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](#).

U.S. 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.

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. 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.
3. 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.
4. Skin conditions by the numbers. American Academy of Dermatology Association, 2021. Available at [Skin conditions by the numbers \(aad.org\)](https://www.aad.org/skin-conditions-by-the-numbers). Accessed September 15, 2021.
5. 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.
6. 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.
7. Elsaie ML. Hormonal treatment of acne vulgaris: an update. *Clin Cosmet Investig Dermatol*. 2016;9:241-248.
8. 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.
9. WINLEVI[®] (clascoterone) cream 1% [prescribing information](#). Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; September 2021.

Contacts

Cosmo

Hazel Winchester,
Head of Investor Relations
Cosmo Pharmaceuticals N.V.
Tel: +353 1 817 03 70
hwinchester@cosmopharma.com

Sun Pharma

Investors:

Nimish Desai
Tel +91 22 4324 4324, Xtn 2778
Direct +91 22 4324 2778
Mobile +91-98203 30182
E mail nimish.desai@sunpharma.com

Media:

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