

Sun Pharmaceutical Industries Limited

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July 26, 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

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 the signing of license and supply agreements with Cassiopea SpA 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**

Ashok I. Bhuta
Compliance Officer
Enclosed: As above



FOR IMMEDIATE RELEASE

Sun Pharma and Cassiopea SpA Announce Signing of License and Supply Agreements for Winlevi® (clascoterone cream 1%) in US and Canada

Mumbai, India and Lainate, Italy, July 26, 2021: Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) and Cassiopea SpA (SIX: SKIN), a specialty pharmaceutical company developing and preparing to commercialize prescription drugs with novel mechanisms of action (MOA) to address long-standing essential dermatological conditions today announced the signing of License and Supply Agreements for Winlevi® (clascoterone cream 1%) in the United States and Canada. Winlevi® has been approved by the United States Food & Drug Administration (FDA) as a novel drug with a unique mechanism of action for the topical treatment of acne in patients 12 years and older.^{1,2}

Under the terms of the above referred agreements, Sun Pharma will have the exclusive right to commercialize Winlevi® in the United States and Canada, and Cassiopea will be the exclusive supplier of the product. Cassiopea will receive an upfront payment of US \$45 million, potential commercial milestones totalling up to US \$190 million and customary double digit royalties. The agreements will close upon the expiration of the HSR waiting period.

Winlevi® is expected to be available in the U.S. in Q4 calendar 2021.

Abhay Gandhi, CEO, North America of Sun Pharma, said: *"Sun Pharma is pleased to enter into a collaboration with Cassiopea SpA. Winlevi® is a new class of topical medication in dermatology and will complement our existing oral acne portfolio. The addition of Winlevi® further strengthens our position in the acne segment and reinforces our deep commitment to caring and making a difference in the lives of patients."*

Diana Harbort, CEO of Cassiopea SpA, commented: *"We are very pleased to partner with Sun Pharma. Sun Pharma has a strong established U.S. dermatology presence and will make Winlevi® widely available to dermatology health care providers and their patients. Following this transaction, Cassiopea will be expecting substantial revenue streams for the foreseeable future and will be well funded to continue the development of its innovative dermatology pipeline."*

The FDA approved Winlevi® (clascoterone cream 1%) in August 2020 for the topical treatment of acne vulgaris in patients 12 years and older.^{1,2} Acne, being the most prevalent skin condition in the U.S., affects up to 50 million Americans annually³. The last FDA approval of an acne drug with a new mechanism of action (MOA) occurred nearly 40 years ago.



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.

About Cassiopea

Cassiopea is a specialty pharmaceutical company developing and commercializing prescription drugs with novel mechanisms of action to address long-standing and essential dermatological conditions, particularly acne, androgenetic alopecia (or AGA) and genital warts. Cassiopea is investing in innovation that is driving scientific advancement in areas that have been largely ignored for decades. The portfolio comprises four unencumbered clinical candidates, for which Cassiopea owns the worldwide rights. The Company's strategy is to leverage this expertise to optimize the commercial potential for its products directly or with a partner. For further information on Cassiopea, please visit www.cassiopea.com.

About Winlevi®

Winlevi® (clascoterone cream 1%) 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.⁴ 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 WINLEVI®. 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. WINLEVI®. Package Insert. Cassiopea. 2020. www.winlevi.com
2. US FDA. Novel Drug Approvals for 2020. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020>. Accessed March 15, 2021.
3. The American Academy of Dermatology. Skin conditions by the numbers. American Academy of Dermatology. <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. Accessed March 15, 2021.
4. Rosette C, et al. *J Drugs Dermatol*. 2019; 18(5):412-418. <https://www.ncbi.nlm.nih.gov/pubmed/31141847>

Some of the information contained in this press release may contain forward-looking statements. Readers are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those in the forward-looking statements as a result of various factors. Neither Cassiopea nor Sun Pharma has any obligation to publicly update or revise any forward-looking statements.

Contacts

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Cassiopea SpA

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