



FOR IMMEDIATE RELEASE

Sun Pharma and Cassiopea announce the expiry of the HSR Act process and the successful consummation of their Winlevi® (clascoterone cream 1%) agreement

Mumbai, India and Lainate, Italy, August 31, 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) 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 expiration of the applicable waiting period under the US Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act) in connection with the exclusive License and Supply Agreements signed by both companies for Winlevi® (clascoterone cream 1%), for which a press release was issued by both companies on July 26, 2021. The agreements are effective as of August 31, 2021.

Sun Pharma now has the exclusive right to commercialize Winlevi® in the United States and Canada. Cassiopea will be the exclusive supplier of the product. Winlevi® is expected to be available in the U.S. in Q4 calendar 2021.

Abhay Gandhi, CEO, North America of Sun Pharma, said: *“The expiration of the applicable waiting period under the HSR Act clears the path for making Winlevi® available to patients and healthcare providers in the US and Canada. With Winlevi®, a unique product with a new mechanism of action for the topical treatment of acne vulgaris, we have further expanded our basket of innovative products to serve patients better.”*

Diana Harbort, CEO of Cassiopea SpA, commented: *“We are very pleased that Winlevi® will soon be widely available to dermatology healthcare providers and their patients in the US and Canada, benefiting from Sun Pharma’s strong established dermatology presence. This transaction now allows Cassiopea to focus on 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 MOA occurred nearly 40 years ago. Most common adverse reactions occurring in 7 to 12% of patients are erythema/reddening, pruritus and scaling/dryness.



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.

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