



## **Cassiopea SpA announces the US launch of Winlevi® (clascoterone cream 1%)**

**Lainate, Italy, November 3, 2021:** 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 US launch effective November 1, 2021, of Winlevi® (clascoterone cream 1%) by its partner, Sun Pharmaceutical Industries Ltd. Winlevi® is the first new MOA approved by the FDA for the treatment of acne in forty years.

Sun Pharma has the exclusive right to commercialize Winlevi® in the United States and Canada. Cassiopea is the exclusive supplier of the product.

Diana Harbort, CEO of Cassiopea SpA, commented: *"We are very pleased that Winlevi® is now widely available to dermatology healthcare providers and their patients in the US, benefiting from Sun Pharma's strong established dermatology presence".*

The FDA approved Winlevi® (clascoterone cream 1%) in August 2020 for the topical treatment of acne vulgaris in patients 12 years and older.<sup>1,2</sup> Acne, being the most prevalent skin condition in the U.S., affects up to 50 million Americans annually.<sup>3</sup> The last FDA approval of an acne drug with a new MOA occurred nearly 40 years ago.

### **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](http://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.<sup>4</sup> Complete prescribing information is available at [www.WINLEVI.com](http://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](http://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 has any obligation to publicly update or revise any forward-looking statements.

## **Contact**

### **Cassiopea SpA**

Diana Harbort, CEO & Head of Investor Relations

Tel +39 02 868 911 24

E-mail [dharbort@cassiopea.com](mailto:dharbort@cassiopea.com)