



Cassiopea Receives FDA Approval for Winlevi® (clascoterone cream 1%), First-in-Class Topical Acne Treatment Targeting the Androgen Receptor

The approval of WINLEVI brings the first truly new mechanism of action in acne treatment in nearly 40 years

Lainate, Italy – August 27, 2020 - Cassiopea SpA (SIX: SKIN), today announced that the United States Food and Drug Administration (FDA) approved Winlevi® (clascoterone cream 1%) for the treatment of acne in patients 12 years and older. Notwithstanding acne being the most prevalent skin condition in the U.S. affecting up to 50 million Americans annually¹, the last FDA approval of an acne drug with a new mechanism of action (MOA) occurred nearly 40 years ago.

Acne is a multifactorial skin condition, affected by four distinct pathways: excess oil (sebum) production, clogged pores (hyperkeratinization), bacteria growth (*C. acnes*), and inflammation². Topical treatment options that target androgens, which largely drive sebum production and inflammation, presented a significant unmet need in the acne treatment market until now.

“The approval of WINLEVI is an exciting breakthrough in acne treatment. This game-changing topical drug offers a non-antibiotic approach to people with acne, by targeting the androgen receptors directly in the skin. It fills a longstanding gap in acne therapy.” said Michael Gold, M.D., Investigator and Medical Director, Gold Skin Care Center and Tennessee Clinical Research Center. “After 40 years, it provides a much-anticipated, complementary new approach to treat acne.”

Cassiopea’s first-in-class topical androgen receptor inhibitor, WINLEVI, tackles the androgen hormone component of acne in both males and females. Androgen receptor inhibitors act by limiting the effects of these hormones on increasing sebum production and inflammation³.

In pivotal clinical trials, WINLEVI demonstrated treatment success and reductions in acne lesions and was well tolerated when used twice a day. The most frequently observed local skin reaction was mild erythema^{4,5}.

Diana Harbort, CEO of Cassiopea, said: “This milestone approval marks the introduction of a new class of topical medication in Dermatology. Dermatologists have said targeting androgen hormonal activity in the skin is ‘the holy grail’ of acne treatment for both males and females. We are proud to bring this new innovation to acne patients. This approval rewards many years of hard work and positions Cassiopea as a leader in Dermatology. Now we look forward to expanding our franchise and advancing our next investigational drug candidate for androgenetic alopecia.”

WINLEVI is expected to be available in the United States in early 2021. Complete prescribing information is available on www.WINLEVI.com.

About Winlevi® (clascoterone cream 1%):

Winlevi® (clascoterone cream 1%) is approved for the treatment of acne vulgaris in people aged 12 and older. Although WINLEVI's exact mechanism of action 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 follicles⁶.

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

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.

About Cassiopea

Cassiopea is a specialty pharmaceutical company developing and commercializing prescription drugs with novel mechanisms of action (MOA) 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. Once approved, the Company plans to commercialize the products directly in the U.S. and partner the products for countries outside of the US. For further information on Cassiopea, please visit www.cassiopea.com.

Next events:

HC Wainwright Annual Global Investors Conference Investora	14-15 September 2020, Virtual 23 September 2020, Zurich
Jefferies Global Health Care Conference	17-19 November 2020, London
Credit Suisse Small & Mid Cap Conference	18-20 November 2020, Zurich

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3. Elsaie ML. *Clin Cosmet Investig Dermatol* 2016;9:241–8.
4. Hebert A, et al *JAMA Dermatol*. 2020;156(6):621-630
5. Eichenfield, L., et al. *JAAD* Published:April 26, 2020.. [https://www.jaad.org/article/S0190-9622\(20\)30703-9/fulltext](https://www.jaad.org/article/S0190-9622(20)30703-9/fulltext)
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<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. Cassiopea has no obligation to publicly update or revise any forward-looking statements.