Cosmo Pharmaceuticals announces FDA Approval for Cassiopea's 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

Dublin, Ireland – August 27, 2020 – Cosmo Pharmaceuticals NV announced today that Cassiopea SpA (SIX: SKIN), a company in which it holds 46.56% of the shares, 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 annually[1], 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 inflammation[2]. 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.

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 inflammation[3].

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 and thank Cosmo Pharmaceuticals for its continued support throughout the development of this important achievement. This approval 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."

Alessandro Della Chà, CEO of Cosmo, stated: "We congratulate the Cassiopea team on this great achievement and are proud to have been part of this. We founded Cassiopea and spun the company off listing it on the SIX in 2015. Cosmo has been supporting the development of Cassiopea through a comprehensive service agreement and has provided extensive financing."

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 follicles[6].

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 Cosmo Pharmaceuticals

Cosmo is a specialty pharmaceutical company focused in treating selected Gastrointestinal Disorders and Endoscopy. The Company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, Colonic Infections and detection of colonic lesions. Cosmo has also developed medical devices for endoscopy and has recently entered into a partnership with Medtronic for the global distribution of its novel Artificial Intelligence device to be used in coloscopies and GI procedures. Further, Cosmo has licensed Aemcolo™ to Red Hill Biopharma and is the licensee for U.S. of the novel agent for procedural sedation, remimazolam, which it has sub-licensed to Acacia. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

Calendar

Investora, Zurich	September 23, 2020
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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