



Cosmo Receives Negative CHMP Opinion on Winlevi® (clascoterone Cream 1%) in Europe and Will Appeal the Decision

Ad hoc announcement pursuant to Art. 53 LR

Dublin, Ireland – April 29, 2025: Cosmo Pharmaceuticals N.V. (SIX: COPN) announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a negative opinion on the marketing authorization application (MAA) for Winlevi® (clascoterone cream 1%) for the treatment of acne vulgaris.

The opinion is principally based on the CHMP's negative benefit-risk assessment on the therapeutic use of Winlevi in adolescents (12 to 17 years of age), despite the fact that such an assessment is demonstrably positive in adults (18 years of age and older). It is plain that the CHMP opinion did not differentiate between these two demographic subsets of the population, probably in view of the fact that the initially submitted application for marketing authorization sought approval for treatment of acne vulgaris in patients from the age of 12 years.

Cosmo will request a re-examination of the adopted opinion as it does not reflect the clinically meaningful and statistically significant beneficial effects of Winlevi in treating patients with acne vulgaris from 12 years and above based on the evidence derived from the two multi-centre, randomised, double-blind clinical trials, and the substantial safety characterization data to support a favorable benefit-risk assessment for the product to be used in adolescents and adults^{1, 2, 3, 4, 5, 6}. The safe and effective conditions of Winlevi are further supported by real-world evidence. In countries where Winlevi is already approved especially the United States where the product has been used safely in adolescents since its approval, no emerging safety concerns have been identified. The growing body of evidence continues to support a favorable benefit-risk balance of the product in adolescents and adults. Cosmo remains confident that Winlevi will serve as a potential treatment option for acne vulgaris which is a common chronic disease that may be associated with impairment of quality of life.

Prof. Andrea Lania, Professor of Endocrinology, Humanitas University, commented: *"As a clinician and researcher, I find the negative opinion difficult to understand given the robust clinical data supporting clascoterone. This is a therapy that has transformed acne management globally, with hundreds of thousands of patients treated. I support Cosmo's intention to appeal and hope the EMA will reconsider this decision in light of the full evidence."*

Giovanni Di Napoli, CEO of Cosmo, added: *"We are surprised and disappointed by the CHMP's opinion, particularly given the well-established safety and efficacy profile of clascoterone in both clinical trials and extensive real-world use in adolescents and adults. While we acknowledge the Committee's recognition of clinical value in adults, we made a deliberate and data-driven decision not to amend the proposed indication to exclude adolescents. This was not a tactical omission, but a principled stance based on robust global experience. In the United States alone, hundreds of thousands of adolescents have safely used Winlevi since approval, without any emerging safety concerns."*

Cosmo believes the CHMP's current position does not reflect the totality of evidence supporting clascoterone across age groups and the urgent need for innovation in acne treatment, particularly for adolescents - the population most impacted by the condition.

¹ Bhatia et al. J. Drugs Dermatol. 2024 . 23(6) : 433-437

² Herbert et al. JAMA Dermatology. 2020. 156(6) : 621-630

³ Eichenfield et al. J. Am. Acad. Dermatol. 2020. 83: 477-485

⁴ Herbert et al. J. Drugs Dermatol. 2023 . 22(2) : 174-181

⁵ Eichenfield et al. J. Drugs Dermatol. 2023. 22(8): 810-816

⁶ Eichenfield et al. J. Drugs Dermatol. 2024. 23(1): 1278-1283



“We remain fully confident in the science behind Winlevi,” continued Di Napoli, “and we look forward to engaging constructively through the re-examination process to ensure that patients across Europe — regardless of age — can access this important therapeutic option.”

Cosmo will continue to engage with the EMA throughout the re-examination process and will provide further updates in due course.

About Winlevi® (clascoterone cream 1%)

Winlevi is the first and only topical androgen receptor inhibitor for acne with a novel mechanism of action in almost 40 years. Winlevi has already been approved for use in both adults and adolescents in the United States, where it received FDA approval in 2020, and was subsequently approved by several other major regulatory agencies, including Health Canada, TGA (Australia) and was recently approved in the United Kingdom. To date, it has been prescribed to hundreds of thousands of patients globally and is widely regarded as a generally well tolerated and effective treatment option^{7, 8, 9, 10, 11, 12}.

About Cosmo

Cosmo Pharmaceuticals N.V. is committed to revolutionizing healthcare and transforming people's lives by researching and developing innovative products that tackle unfulfilled healthcare demands. As a pharmaceutical company, Cosmo is active in the areas of Healthtech/AI, dermatology, gastroenterology and contract manufacturing & development. For the commercialization and distribution of its products, Cosmo collaborates with leading partners worldwide, including Medtronic and Sun Pharma. Founded in 1997, Cosmo is headquartered in Dublin (Ireland) and has offices also in San Diego (USA), and Lainate/Rome/Catania (Italy). The Company has approximately 330 employees at the end of 2024, all dedicated to making a significant impact in the field of healthcare. For more information, please visit www.cosmopharma.com.

Financial calendar

Ordinary Annual General Meeting of Shareholders	May 30, 2025
Jefferies Healthcare Conference, New York	June 3-5, 2025
Investor Day, Zurich	July 1, 2025
2025 Half-Year Results and Report	July 23, 2025

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⁷ Del Rosso et al. The Journal of Dermatological Treatment. 2024. 35(1), 2298878.

⁸ Manjaly et al. Drugs of Today. 2023. 59(2): 71–81.

⁹ Peterson et al. Journal of Drugs in Dermatology. 2023. 22(6 - Supplement 1): s7-s14.

¹⁰ Burma et al. Skin Therapy Letter 2022. “Topical Clascoterone for Acne Vulgaris”.

¹¹ Lynde et al. J. Drugs Dermatol. 2025. 24(1 - Supplement 2): s3-s14.

¹² Tay & Loo. Clinical, Cosmetic and Investigational Dermatology. 2025. 18: 161–167.