



Cosmo Receives Positive CHMP Opinion for Winlevi® for Treatment of Acne in Adults and Adolescents, Following Successful Re-examination

Dublin, Ireland – August 27, 2025: Cosmo Pharmaceuticals N.V. (SIX: COPN), a global leader in AI-powered healthcare and specialty pharma, today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending European approval of Winlevi® (clascoterone 1% cream) for the treatment of facial acne vulgaris in both adults and adolescents aged 12 to <18 years. The decision follows a successful re-examination of the initial negative CHMP opinion issued in April.

This recommendation for approval marks a significant expansion of Winlevi®'s European indication and positions Cosmo to deliver a first-in-class topical anti-androgen therapy to the largest acne treatment segment in the region. Winlevi® is already approved in the United States, Canada, the United Kingdom, Australia, Malaysia, Singapore and Jordan markets.

"The recommendation for approval by CHMP is a major strategic milestone for Cosmo," said Giovanni Di Napoli, CEO of Cosmo. "It reflects the strength of our science, the quality of our engagement with regulators, and our deep commitment to advancing care in dermatology. Most importantly, it brings a breakthrough therapy to millions of adolescents and adults suffering from acne. This outcome is fully aligned with our Vision 2030 and unlocks a significant growth opportunity across Europe."

In its previous review, the CHMP concluded that the benefit-risk balance of Winlevi® was negative for therapeutic use in adolescents (12 to <18 years of age), while considering the product approvable in adults; it recommended refusing marketing authorization for the indication Cosmo had applied for, namely the treatment of acne vulgaris in patients 12 years of age and older.

Following the initial CHMP refusal, Cosmo initiated a formal re-examination procedure and provided a deeper clinical assessment supported by leading dermatology experts and an expert Professor of endocrinology. The procedure also included the consultation of an Ad-Hoc Expert Group comprising dermatologists and endocrinologists. The CHMP has now concluded that the benefit-risk profile of Winlevi® is favourable for both adults and adolescents, recommending for the approval in both age groups, with usage in adolescents limited to facial application.

"This is a real breakthrough," said Prof. Brigitte Dréno, founder member of the European Association of Dermato-Oncology, past president of the French Society of Dermatology, and member of the American Academy of Dermatology. "We've been waiting for an innovation like this – a topical anti-androgen that is well-tolerated, effective, and safe for adolescents. It will be a valuable addition to our treatment options."



Winlevi® acts by inhibiting androgen receptors in the skin, reducing sebum production and inflammation – two key drivers of acne pathogenesis. Its novel mechanism of action, combined with minimal systemic absorption, makes it a compelling treatment option for both physicians and patients.

The adolescent population represents a large proportion of acne patients in Europe, and until now, had no access to a topical anti-androgen solution. The positive CHMP opinion significantly expands Winlevi®'s addressable market and is expected to materially contribute to Cosmo's mid- and long-term growth trajectory.

Cosmo is already working at full speed with its commercial partners to prepare for launch across 20 European markets. *"We are executing with urgency," Cosmo-CEO Giovanni Di Napoli added. "This is Cosmo at its essence – focused, science-led, and relentlessly committed to delivering impact for patients and shareholders alike."*

A full summary of the product characteristics for Winlevi® are available from the EMA website at www.ema.europa.eu. Winlevi®, Cosmo and Cosmo logo are trademarks of Cosmo Pharmaceuticals N.V. or its related companies.

About Cosmo

Cosmo is a life sciences company focused on MedTech AI, dermatology, gastrointestinal diseases, and contract development and manufacturing (CDMO). We design, develop, and manufacture advanced solutions that address critical medical needs and raise the standard of care. Our technologies are trusted by leading global pharmaceutical and MedTech companies and reach patients and healthcare providers around the world. Guided by our purpose - Building Health Confidence - our mission is to empower patients, healthcare professionals, and partners by innovating at the intersection of science and technology. Founded in 1997, Cosmo is headquartered in Dublin, Ireland, with offices in San Diego (USA), and in Lainate, Rome, and Catania (Italy). For more information, visit www.cosmohealthconfidence.com

Financial calendar

H.C. Wainwright 27th Annual Global Investment Conference, New York City, USA
Jefferies Global Healthcare Conference, London, United Kingdom
ODDO BHF Forum, Lyon, France

September 8-10, 2025
November 17-20, 2025
January 8-9, 2026

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