Cosmo Pharmaceuticals receives regulatory approval by the European Commission for Winlevi® in the EU, following on the positive CHMP opinion

Dublin, Ireland – October 21, 2025: Cosmo Pharmaceuticals N.V. (SIX: COPN), a global leader in AI-powered healthcare and specialty pharma, today announced that the European Commission has granted regulatory approval in the EU for Winlevi® (clascoterone 1% cream) for the treatment of acne vulgaris in both adults and adolescents aged 12 to <18 years, with usage in adolescents limited to facial application. This formal approval came following on the positive recommendation for approval by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) on 25th of August 2025. Cosmo is already working at full speed with its commercial partners to prepare for launch across 20 European markets.

Acne vulgaris is among the most common skin conditions worldwide, affecting over 90 percent of people at some point in their lives and often leading to both physical and emotional consequences, including reduced self-esteem and quality of life. Conventional topical therapies can cause irritation or limited tolerability, and few options directly target the hormonal component of acne.

Winlevi® is the first topical acne therapy in more than 40 years with a first-in-class mechanism of action. Its active ingredient, clascoterone, is the first commercially available topical androgen-receptor inhibitor acting locally in the sebaceous glands to reduce sebum production and inflammation without systemic anti-androgen effects, supporting safe use in both males and females.

Giovanni Di Napoli, CEO of Cosmo, commented: *"The regulatory approval of Winlevi® by the European Commission is another major corporate milestone for us in 2025. We expect it to contribute significantly to our Company's mid- and long-term growth. We are also delighted that we can now offer our compound to adolescents in Europe, who previously had no access to a topical anti-androgen solution for treating acne."*

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, said: *"It's exciting to see Winlevi® finally completed all regulatory milestones and is now ready for commercialisation. The dermatology community has been eager for a genuine breakthrough in acne therapy, a topical anti-androgen that's both effective and well tolerated, including in adolescents. This is a meaningful advancement and a welcome new option for our patients."*

Winlevi® has already been approved in the United States, Canada, Australia, the United Kingdom, New Zealand, Jordan, Singapore, Malaysia, Mexico, South Korea, Kuwait and Egypt. Additional

registrations are progressing as Cosmo and its partners continue to expand commercial access to this innovative acne therapy globally.

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

Jefferies Global Healthcare Conference, London, United Kingdom	November 17-20, 2025
Berenberg European Conference, Windsor, United Kingdom	December 1-4, 2025
ODDO BHF Forum, Lyon, France	January 8-9, 2026

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