# Winlevi® Receives Regulatory Approval in Brazil – Expanding Global Access to a Breakthrough Acne Treatment

**Dublin, Ireland – November 14, 2025:** Cosmo Pharmaceuticals N.V. (SIX: COPN), a global leader in AI-driven healthcare and dermatology innovations, today announced that the Brazilian Health Regulatory Agency (ANVISA) has approved Winlevi® (clascoterone) cream 1% for the treatment of acne vulgaris in patients aged twelve years and older. This milestone marks another key step in Cosmo's mission to build health confidence worldwide, expanding access to its first-in-class topical anti-androgen to one of the largest dermatology markets in Latin America. With approval already granted in the Mexican market, availability of Winlevi® extends to over 50% of the Latin American population.

Winlevi® is commercialized globally through Cosmo's network of strategic partners. In Brazil, Cosmo's long-standing partner Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) will launch the product. Following on the United States, Canada, Australia, the United Kingdom, New Zealand, Jordan, Singapore, Malaysia, Mexico, South Korea, Egypt, and the European Union (20 countries), Brazil is the thirteenth territory where Winlevi® has been approved so far. Additional registrations are progressing as Cosmo and its partners continue to bring this innovative acne therapy to patients around the world.

Acne vulgaris is among the most common skin conditions globally, affecting more than 90% of people at some point in their lives and often having a significant impact on self-esteem and quality of life. Winlevi® represents the first new class of topical acne treatment in over 40 years. Its active ingredient, clascoterone, is the first topical androgen receptor inhibitor, acting locally on the sebaceous glands to reduce sebum production and inflammation without systemic hormonal effects, making it suitable for both male and female patients.

**Giovanni Di Napoli, CEO of Cosmo, commented:** *"The approval of Winlevi® in Brazil is more than a regulatory milestone – it's another step forward in our global dermatology expansion. Acne affects confidence as much as skin, and Winlevi® offers patients a truly innovative option to restore both. This achievement strengthens our partnership with Sun Pharma and reinforces Cosmo's commitment to deliver differentiated, patient-focused solutions around the world – perfectly in line with our Vision 2030 growth strategy."*

**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**

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| Jefferies Global Healthcare Conference, London, UK | November 19, 2025 |
| Berenberg European Conference, Windsor, UK | December 4, 2025 |
| ODDO BHF Forum, Lyon, France | January 8-9, 2026 |
| 2025 FY results, Annual report and ESG Report | Week of March 9, 2026 |

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