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Cosmo announces breakthrough Phase III Topline results from Scalp 1 and Scalp 2 for Clascoterone 5% Solution in male hair loss, showing up to 539% relative improvement in Target-Area Hair Count vs placebo; US and EU submissions are underway

Ad hoc announcement pursuant to Art. 53 LR

- **1,465 patients were randomized into the two identical-in-design clinical studies Scalp 1 (NCT05910450) and Scalp 2 (NCT05914805)**
- **Both studies reached statistically significant endpoints in TAHC (Target-Area Hair Count), with one reaching 539% relative improvement to placebo and the second study reaching 168% relative improvement to placebo**
- **Positive safety profile demonstrated across both studies**
- **Largest Phase III program ever conducted for a Topical Treatment for Male Androgenetic Alopecia (AGA)**
- **First novel mechanism of action and first potential innovation in over 30 years in male hair loss**
- **Preparations are underway for parallel regulatory submissions in the United States and Europe**

Dublin, Ireland – December 3, 2025: Cosmo Pharmaceuticals N.V. (SIX: COPN), a global leader in AI-powered healthcare and specialty pharma, today announced compelling topline results from its two pivotal Phase III trials of clascoterone 5% topical solution for male androgenetic alopecia (AGA, also known as male-pattern hair loss), marking a potential first major therapeutic breakthrough in hair-loss treatment in more than three decades.

Across 1,465 patients enrolled in two identically designed Phase III studies conducted in the United States and Europe, clascoterone 5% solution delivered robust, statistically significant ($p<0.05$), and clinically meaningful improvements with a safety and tolerability profile comparable to the placebo vehicle. One study demonstrated a 5.39x (539 percent) relative improvement in Target-Area Hair Count (TAHC) versus vehicle, while the second study showed a 1.68x (168 percent) relative improvement. Treatment Emergent Adverse Events (TEAEs) were similar across both studies, and similar to vehicle, with most TEAEs not related to study drug.

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Patient-reported outcomes (PROs) further reinforced the strength of the Topline Phase III results. One study PRO endpoint reached statistical significance and the other study PRO showed a positive trend, while the combined analysis across both studies was statistically significant and fully consistent with the objective THAC measures, confirming that patients both experienced and perceived meaningful improvement.

These findings represent a significant advance in a condition that affects 1.2 to 2 billion men worldwide and is recognized for its emotional and social impact. Studies show that clascoterone 5% topical solution is completely new therapeutic approach to treating AGA. In blocking dihydrotestosterone (DHT) directly at the hair-follicle receptor without systemic absorption, clascoterone 5% topical solution is the first topical androgen receptor inhibitor designed to target the biological root cause of male-pattern hair loss without the risks associated with oral therapies. Unlike existing therapies, clascoterone 5% solution was developed specifically for AGA.

"*These data reflect a significant milestone for patients with male pattern hair loss,*" **said Dr. Maria Hordinsky, MD, R.W Goltz Professor of Dermatology, University of Minnesota, Department of Dermatology.** *"For decades, patients have had to choose between available treatment options with limited efficacy or safety issues due to systemic hormonal exposure, often resulting in patients not treating their hair loss at all. These findings show the potential for clascoterone 5% topical solution to change that equation by delivering real, measurable regrowth with negligible systemic exposure. These data have the potential to redefine how dermatologists treat androgenetic alopecia worldwide."*

Commenting on the results, **Giovanni Di Napoli, CEO of Cosmo, said:** *"This is a pivotal moment for Cosmo and for billions of men worldwide who struggle every day with the emotional and social impact of hair loss. Androgenetic alopecia is far more than a cosmetic issue – it affects confidence, identity, and emotional well-being. For the first time in more than thirty years, we have a completely new mechanism with the potential to truly change that reality."* ***Di Napoli added:*** *"With strong efficacy across the two largest Phase III studies, and a favorable safety profile, clascoterone 5% topical solution opens the door to a fundamentally better treatment paradigm for patients. At our Investor Day in July, Cosmo presented in-depth U.S. market research results showing an enormous, underserved demand. These compelling data give us full confidence in respect to the upcoming regulatory submissions. We strongly believe that clascoterone 5% topical solution will deliver meaningful benefit to patients."*

Cosmo is on track to complete the required twelve-month safety follow-up in spring 2026. Upon completion of the full dataset, Cosmo plans to promptly pursue parallel regulatory submissions in the United States and Europe. Clascoterone 5% topical solution is positioned to become the first topical androgen receptor inhibitor ever approved for AGA, subject to regulatory authorization.

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Investor snapshot

- Indication: Male androgenetic alopecia
- Patients: 1,465 across two Phase III studies, largest Phase III studies conducted for topical treatment in male AGA
- Efficacy: 5.39x (539 percent) and 1.68× (168 percent) relative improvements vs Vehicle
- PRO: Statistically significant for the two Phase III studies combined
- Safety: Positive tolerability, TEAEs similar across both studies and similar to vehicle
- Mechanism: First topical androgen receptor inhibitor; first innovation in 30 years
- Patents: Valid through 2036
- Market: >$20B U.S. opportunity confirmed by Cosmo market research
- Next Milestone: Parallel FDA/EMA submissions upon completion of 12-month safety

About Clascoterone

Clascoterone 5% topical solution leverages the same active ingredient used in Winlevi®, Cosmo's FDA and EMA approved topical acne treatment, supported by a well-established dermatologic safety profile and Cosmo's proprietary formulation technology. Winlevi® is the #1 branded prescription topical acne product in the US with over ~1.6 million prescriptions written since launch.

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

Berenberg European Conference, Windsor, United Kingdom	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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