Phase III 12-Month Data for Clascoterone 5% Topical Solution Confirm Positive Safety for Chronic Use and Continued Hair Growth, both of which Are Statistically Significant

Ad hoc announcement pursuant to Art. 53 LR

- Long-term safety profile comparable to vehicle supports suitability for chronic use in a lifelong condition.
- Patients who remained on continuous Clascoterone treatment continued to gain hair through Month 12. In contrast, patients who switched to the placebo from Month 7 onwards experienced a reduction in treatment gains, demonstrating the importance of ongoing therapy.
- NDA and MAA preparations underway, U.S. filing planned for early 2027.

Dublin, Ireland – April 15, 2026: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) ("Cosmo") today announced positive 12-month Phase III results for Clascoterone 5% topical solution in men with mild-to-moderate androgenetic alopecia (AGA), reinforcing the product's potential to redefine treatment in one of the largest and most underserved categories in dermatology. The data confirm three critical attributes physicians and patients have been waiting for: long-term safety, continued efficacy with ongoing use, and a novel mechanism designed to target the underlying biology of hair loss.

The Phase III program, composed of SCALP 1 and SCALP 2 pivotal studies, enrolled 1,465 subjects across 51 study centers in the United States and Europe, thereby making it the largest Phase III clinical program ever conducted for a topical treatment in male AGA. The 12-month extension evaluated long-term safety and durability of effect in patients who were responders in the first 6-month study period (Part 1) and could therefore participate in Part 2, where they were re-randomized to either continue Clascoterone 5% solution or switch to vehicle for the additional 6-month treatment period.

Giovanni Di Napoli, Chief Executive Officer of Cosmo, said: *"These 12-month Phase III results mark a defining moment for Clascoterone and for the treatment of male hair loss. We are now seeing the combination that matters most: positive long-term safety, statistically significant continued hair growth through one year, and clear evidence that ongoing treatment drives sustained benefit. In a disease that has seen limited innovation for decades, Clascoterone has the potential to emerge as a major new therapeutic option and a highly valuable growth platform for Cosmo. We are moving with urgency toward regulatory submissions and commercialization discussions."*

Positive Safety Profile Supports Chronic Use

Male AGA is a chronic progressive condition that often begins early and requires years of treatment. For that reason, long-term tolerability is essential.

Across 12 months of treatment, Clascoterone maintained a safety and tolerability profile comparable to vehicle, with no significant systemic hormonal side effects observed. These findings are consistent with the negligible systemic absorption previously seen in earlier clinical studies and support Clascoterone as a long-term treatment option appropriate for a safe chronic use.

Maria Hordinsky, MD, Professor of Dermatology at the University of Minnesota and clinical investigator in the Phase III program, said: *"AGA requires long-term management, so safety matters enormously. These data are encouraging because they show a profile that supports chronic use over time."*

Continued Hair Growth Through 12 Months with Statistically Significant Benefit

The most important efficacy finding from the 12-month dataset was clear: patients who stayed on Clascoterone kept improving, while patients who stopped active treatment showed a decline in hair count.

Patients who remained on Clascoterone for the full 12 months achieved a statistically significant 2.39x improvement in Target Area Hair Count (TAHC) versus patients who received Clascoterone for six months and were then switched to vehicle from month 7 to month 12.

These findings show more than efficacy. They show durability, continued biological activity over time if treatment is maintained, and treatment-dependent effects.

Clascoterone patients continued to gain hair from Month 3 to Month 12 with ongoing treatment. In contrast, patients switching from active therapy to vehicle after Month 6 experienced a measurable and meaningful decline in hair count.

Patient-reported outcomes further supported the data. Subjects treated with Clascoterone for 12 months reported a statistically significant **+24.5% relative improvement in treatment satisfaction** versus vehicle groups.

Notably, patients also reported positive ease of use and product acceptability at Month 12, supporting positive real-world usability and long-term adherence potential.

First Novel Mechanism in Over 30 Years Targeting the Root Cause of Hair Loss

Androgenetic alopecia is one of the largest and most underserved categories in medical dermatology.

Despite this clear unmet need, innovation in male AGA has been limited for decades.

Clascoterone topical solution is designed to locally inhibit androgen receptor signalling in the scalp, directly targeting one of the key biological drivers of follicle miniaturization and progressive hair loss. By addressing the disease process at the level of the androgen receptor in the scalp, Clascoterone has the potential to offer a differentiated therapeutic approach rather than simply managing visible symptoms.

If approved, Clascoterone would represent the **first novel mechanism of action introduced for male AGA in more than 30 years**, offering physicians and patients a new option for a clear unmet need.

Michael H. Gold, MD, FAAD, Founder of Gold Skin Care Center, said: *"Male pattern hair loss is far more than a cosmetic concern. It affects confidence, identity, emotional wellbeing, and quality of life for millions of men every day. Yet physicians have had very few truly new tools to offer patients for decades. Seeing a potential new FDA approved topical treatment with a differentiated mechanism, a favorable safety profile, and efficacy that continues through 12 months is highly meaningful. Clascoterone has the potential to redefine the treatment landscape in male AGA, unlock significant value in a large underserved market, and become the long-awaited new standard of care for patients seeking meaningful regrowth with strong tolerability."*

Next Steps

Cosmo is advancing preparations for a New Drug Application (NDA) in the United States and a Marketing Authorization Application (MAA) in Europe. A U.S. FDA filing is currently planned for early 2027.

The Company also plans to submit the full Phase III dataset for publication in a leading peer-reviewed medical journal and presentation at major dermatology congresses, further engaging the scientific community and expanding awareness of these findings.

Appendix

About SCALP 1 and SCALP 2

The Phase III program consists of two identically designed, multicenter, randomized, vehicle-controlled studies in men with AGA (**SCALP 1** and **SCALP 2**). A total of 1,465 men with mild to moderate aged over 18 years were enrolled across the United States and Europe. Each study included a Pivotal Part 1 six-month double-blind treatment phase in which participants were randomized to receive either Clascoterone 5% solution or a vehicle solution designed to evaluate safety and efficacy.

This was followed by a Part 2 six-month single-blind extension phase in men who responded positively on the PRO survey, which was designed to evaluate long-term safety and durability of treatment in line with FDA guidance. During this extension, participants were re-randomized to receive either Clascoterone 5% solution or vehicle solution.

Efficacy in the SCALP trials was evaluated at six months using co-primary endpoints that incorporated both objective and patient-reported measures. The primary objective endpoint was the change from baseline in TAHC. This was paired with a patient-reported outcome assessing participants' perception of hair growth improvement. Additional assessments, including investigator-reviewed global scalp photography and secondary endpoints, were conducted to provide supportive evidence of treatment effect alongside the primary efficacy endpoints.

About Androgenetic Alopecia
Androgenetic alopecia, also known as male pattern hair loss, is the most common cause of hair loss in men, affecting approximately 40% of men worldwide and 65 million men in the United States. It is caused by the genetic sensitivity of hair follicles to androgens, leading to follicle miniaturization and eventual hair loss. For more information about androgenetic alopecia, including its causes, progression, and impact, please visit our website **here.**

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 ~1.8 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

Van Lanschot Kempen Life Science Conference, Amsterdam	April 16, 2026
TP ICAP Conference, Paris	May 7, 2026
Half-Year 2026 Results and Report	Week of July 20, 2026

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