

Cosmo and Glenmark Announce UK MHRA Approval of Winlevi® for Treatment of Acne

Dublin, Ireland and Mumbai, India | London, U.K. – February 10, 2025: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“Cosmo”) and Glenmark Pharmaceuticals Limited (Glenmark), a global research-led pharmaceutical company, today announced that Glenmark had received approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to market Winlevi® in the United Kingdom. Winlevi® is a topical treatment for acne vulgaris in patients aged 12 years and older, marking a significant milestone in the commitment of both companies to providing innovative, patient-focused dermatology solutions.

Winlevi® is the first topical acne treatment in nearly 40 years with a first-in-class mechanism of action. Its active ingredient, clascoterone, is the first commercially available topical androgen receptor inhibitor, targeting androgen receptors in sebaceous glands with no systemic anti-androgen effects, and as such it can be used safely in both males and females. This approach is believed to help reduce sebum production and intervene early in acne pathogenesis. Two identical phase 3 studies demonstrated that clascoterone cream, 1%, applied topically twice daily for 12 weeks, was more effective than the application of vehicle cream in achieving the Investigator’s Global Assessment (IGA) of success, reducing non-inflammatory lesion count (NILC) and inflammatory lesion count (ILC) in patients with facial acne vulgaris. clascoterone cream, 1%, was generally well tolerated.

As part of the agreement signed in September 2023, Glenmark has in-licensed the product from Cosmo Pharmaceuticals for distribution in Europe and South Africa. This collaboration underscores Glenmark’s and Cosmo’s dedication to expanding its dermatology portfolio and addressing the unmet needs of patients with acne vulgaris, a condition that affects millions of individuals worldwide and can cause both physical discomfort and psychological distress.

Giovanni Di Napoli, Chief Executive Officer of Cosmo, commented: “We are thrilled that Winlevi® has been approved for the UK market, bringing an innovative approach to acne treatment. This milestone underscores our commitment, alongside Glenmark, to providing patients with breakthrough solutions that address not just the physical symptoms of acne, but also its emotional impact. We take great pride in expanding access to this game-changing therapy and making a real difference in patients’ lives.”

"We are excited to receive the approval and bring Winlevi® to the UK market, offering patients a new and efficacious treatment for acne," said **Christoph Stoller, President & Business Head - Europe and Emerging Markets, Glenmark Pharmaceuticals.** "This approval by the MHRA represents a significant step forward in our mission to enhance dermatology care. Our partnership with Cosmo Pharmaceuticals plays an important role in enabling us to expand our dermatology portfolio, and we are proud to offer this new treatment to market that can improve the quality of life for those living with acne."

“The approval of Winlevi® for the UK market marks a crucial milestone in Glenmark’s ongoing efforts to evolve dermatology treatments,” said **Xavier Mesrobian, Executive Vice President and Business Head – Europe, Glenmark SA**. “We are focused on delivering therapies that address the clinical needs of patients and with Winlevi®, we are looking forward to offering an efficacious treatment option for individuals managing acne, a condition that can significantly impact self-confidence and daily life.”

Acne vulgaris is one of the most common skin conditions, impacting more than 90% of the world’s population at some point in their lives. It can have both physical and emotional consequences, affecting individuals’ self-esteem and mental health.

About Glenmark

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is a research-led, global pharmaceutical company, having a presence across Branded, Generics, and OTC segments; with a focus on the therapeutic areas of respiratory, dermatology, and oncology. The company has 11 world-class manufacturing facilities spread across 4 continents, and operations in over 80 countries. In Vivo/Scrip 100 positions Glenmark amongst the Top 100 Companies Ranked by R&D and Pharmaceutical Sales, 2022; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilar Companies Ranked by Sales, 2022. Glenmark’s Green House Gas (GHG) emission reduction targets have been approved in 2023 by the Science Based Target initiative (SBTi), making it only the second pharmaceutical company in India to achieve this. The organization has impacted over 3.3 million lives over the last decade through its CSR interventions.

About Cosmo

Cosmo Pharmaceuticals N.V. is committed to revolutionizing healthcare and transforming people’s lives by researching and developing innovative products that tackle unfulfilled healthcare demands. As a pharmaceutical company, Cosmo is active in the areas of Healthtech/AI, dermatology, gastroenterology and contract manufacturing & development. For the commercialization and distribution of its products, Cosmo collaborates with leading partners worldwide, including Medtronic and Sun Pharma. Founded in 1997, Cosmo is headquartered in Dublin (Ireland) and has offices also in San Diego (USA), and Lainate/Rome/Catania (Italy). The Company has approximately 330 employees at the end of 2024, all dedicated to making a significant impact in the field of healthcare. For more information, please visit www.cosmopharma.com.

Financial calendar

2024 Full-Year Results (unaudited)	March 6, 2025
J.P. Morgan European Opportunities Forum, London	March 12, 2025
2024 Annual Report Publication	March 20, 2025
26th Kepler Cheuvreux Swiss Seminar, Zurich	March 20, 2025
Life Sciences Conference, Amsterdam	April 2-3, 2025
2025 Half-Year Results and Report	July 23, 2025

For further information, please contact

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