

Press Release

For Immediate Release

Cosmo and Glenmark announce the signing of Distribution and License Agreements for Winlevi® in Europe and South Africa

- *Cassiopea, the subsidiary of Cosmo, will be responsible for Centralized Marketing Authorization at European Medicines Agency, while Glenmark will undertake registration of the product in South Africa and in the UK.*
- *Cassiopea will receive an upfront payment of USD 5 million, in addition to double-digit regulatory and sales milestones as well as agreed double-digit royalties on net sales.*

Dublin, Ireland and Mumbai, India – September 27 2023: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“Cosmo”) and Glenmark Specialty S.A., a subsidiary of Glenmark Pharmaceuticals Ltd. (“Glenmark”), today announced the signing of distribution and license agreements for Winlevi® (clascoterone cream 1%) in Europe and South Africa.

Under the terms of the agreements, Glenmark will receive from Cassiopea, a subsidiary of Cosmo, the exclusive right to commercialize Winlevi® in 15 EU countries (Bulgaria, the Czech Republic, Denmark, Finland, France, Hungary, Iceland, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain and Sweden) as well as in South Africa and the UK. Cassiopea shall be responsible for the Centralized Marketing Authorization at the European Medicines Agency (EMA), and Glenmark will be responsible for the registration of the product in South Africa and in the UK. Cosmo will be the exclusive supplier of the product. Cassiopea will receive an upfront payment of USD 5 million, further double-digit regulatory and sales milestones and agreed double-digit royalties on net sales.

Alessandro Della Chà, CEO of Cosmo, said, “We are very pleased to partner with Glenmark. Their strong expertise in the commercialization of pharmaceutical compounds gives us great confidence in their ability to successfully market Winlevi®. We look forward to eventually making Winlevi® available to more patients around the globe.”

“We are delighted to have undertaken this exclusive licensing agreement with Cosmo Pharmaceuticals. Winlevi® is the perfect addition to our European dermatology portfolio and we look forward to leveraging our half-century long experience in dermatology to make this novel option available to patients and fill the current unmet medical need in treating acne,” remarked Glenn Saldanha, Chairman & Managing Director Glenmark Pharmaceuticals Ltd.

Professor Alison Layton (Associate Medical Director for Research, Harrogate and District NHS Foundation Trust) concludes: “The ability to reduce sebum in acne with a topical agent has up until now been a significant unmet need. Sebum is integral in the pathophysiology of all acne severities. Whereas there are effective systemic therapies including oral isotretinoin for severe acne and hormonal treatments for females, these are not advocated or tolerated by all people with acne. Clascoterone offers a novel topical approach for acne. In vitro testing suggests it is the first topical agent to reduce androgen-regulated lipid and inflammatory cytokine production in human primary sebocytes. It could be prescribed as monotherapy or as part of an acne regime including fixed topical combinations and / or systemic antibiotics. All patient populations with acne could potentially receive and benefit from clascoterone.”

Winlevi® has been approved by the United States Food & Drug Administration (U.S. FDA) as a novel drug with a unique mechanism of action for the topical treatment of acne in patients aged 12 years and older. It is a first-in-class topical androgen receptor inhibitor that tackles the androgen hormone component of acne and is the first new mechanism of action in acne approved by the U.S. FDA since 1982. Winlevi® has become the most prescribed branded topical acne drug in the U.S.; with over 15,000 U.S. health care providers, representing 88% of total health care providers in dermatology, having prescribed Winlevi® to date (per IQVIA MAT June 2023). According to the prescriptions generated as measured by IQVIA data, Winlevi® has been one of the most successful U.S. launches in the topical acne space in the last 15 years.

The EU acne market is projected to grow from USD 928.7 million in 2021 to USD 1,297.0 million in 2028. Across Europe, over 90% of people aged 11 to 30 years are affected by acne; with a rising prevalence among teenagers, which is driving the market's growth.

European guidelines discourage the use of topical antibiotics for comedonal acne due to the risk of antibiotic resistance, and despite the many treatments currently available there is still a clear unmet need. With its non-antibiotic approach and by targeting the androgen receptors directly in the skin, Winlevi® addresses aspects of underlying acne causing disease pathways by decreasing sebum production and inflammation. It has the potential to be the first product with an innovative mechanism of action to be available to patients in Europe in over 40 years.

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About Glenmark

Glenmark Pharmaceuticals Ltd. (BSE: 532296 | NSE: GLENMARK) is an integrated, research-led, global pharmaceutical company, with a presence across Branded, Generics, and OTC segments; with a focus on therapeutic areas of respiratory, dermatology and oncology. The company has 10 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, 2021; while Generics Bulletin/In Vivo places it in the Top 50 Generics and Biosimilars Companies Ranked by Sales, 2021. The company has also been Great Place To Work® Certified™ in India. Glenmark's Green House Gas (GHG) emission reduction targets have been approved in 2023 by the Science Based Target initiative (SBTi), becoming the second Indian Pharmaceuticals company to achieve this approval. The organization has impacted over 2.9 million lives over the last decade through its CSR interventions. For more information, visit www.glenmarkpharma.com. You can follow us on LinkedIn (Glenmark Pharmaceuticals) and Instagram ([glenmark_pharma](https://www.instagram.com/glenmark_pharma)).

About Cosmo

Cosmo is a pharmaceutical company focused on developing and commercialising products to treat selected gastrointestinal disorders, to improve endoscopy quality measures through aiding the detection of colonic lesions and to treat selected dermatological conditions. Cosmo develops and manufactures products which are distributed globally by selected partners including Lialda®/ Mezavant®/ Mesavancol®, Uceris®/ Cortiment®, Aemcolo® and Winlevi®. Cosmo has also developed medical devices for endoscopy and has a partnership with Medtronic for the global distribution of GI Genius™ which uses artificial intelligence to help detect potential signs of colon cancer. The company also has a rich development pipeline. For additional information on Cosmo and its products please visit the Company's website: www.cosmopharma.com

Upcoming Calendar of Events

Investor Access, Paris

October 9-10, 2023

Jefferies London Healthcare Conference 2023

November 14-16, 2023

CF&B Communication European Midcap Event, Geneva

December 5, 2023

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