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UK gives nod to Glenmark Pharma's Winlevi for treatment of acne

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Acne vulgaris is one of the most common skin conditions, impacting more than 90% of the world's population



Mumbai-based Glenmark Pharmaceuticals has 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 Ireland-based Cosmo Pharmaceuticals for distribution in Europe and South Africa.

According to 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."