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India's Sun Pharmaceuticals announces approval of Winlevi in Australia for acne treatment

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Expanding dermatology portfolio of innovative medicines in Australia



India-based Sun Pharmaceutical Industries has announced that the Australian Therapeutic Goods Administration (TGA) has granted regulatory approval for Winlevi (clascoterone cream 1%). Winlevi is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

As stated by Hellen de Kloet, Business Head – Western Europe, Australia and New Zealand, Sun Pharma, “Winlevi is an exciting addition to our expanding dermatology portfolio of innovative medicines in Australia. Winlevi’s novel mechanism of action will be a welcome addition to the physician’s toolkit while treating acne.”

Diana Harbort, President of the Dermatology Division of Cosmo, said, “We are very pleased that Winlevi will soon be available to patients in Australia. This is another achievement in the mission of Cosmo and Sun Pharma to improve the lives of patients affected by skin conditions.”

Although the exact mechanism of action for Winlevi is unknown, laboratory studies suggest the active ingredient, clascoterone, competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles.

Sun Pharma has received from Cosmo the exclusive right to develop and commercialise Winlevi in US, Japan, Australia, New Zealand, Brazil, Mexico and Russia.