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March 19, 2024

National Stock Exchange of India Limited
Scrip Symbol: SUNPHARMA

BSE Limited
Scrip Code: 524715

Subject: Press Release - Approval of Winlevi® in Australia

Enclosed herewith is a copy of the Press Release relating to Australian Therapeutic Goods Administration (TGA) approval for Winlevi®, which shall be released after this intimation.

For **Sun Pharmaceutical Industries Limited**

(Anoop Deshpande)
Company Secretary and Compliance Officer
ICSI Membership No.: A23983

FOR IMMEDIATE RELEASE

Sun Pharmaceuticals announces approval of Winlevi® in Australia

Mumbai, March 19, 2024: Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) (“Sun Pharma”) 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.”

Winlevi® will be available in Australia this June. For more information visit <https://sunpharma.com/australia>

About Winlevi®

Winlevi® is approved for the topical treatment of acne vulgaris in people 12 years of age and older. 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 follicles¹.

Androgens are widely recognized as the most important of all hormones in terms of regulating sebum production². Within the skin, androgens bind to androgen receptors, causing increased sebum production and inflammation³. In particular, the skin of patients with acne vulgaris produces higher levels of the androgens testosterone and dihydrotestosterone (DHT) than the skin of healthy individuals⁴.

Winlevi® binds to the androgen receptor competing with androgens such as DHT on cells within the sebaceous gland. Although its precise mechanism of action is unknown, studies suggest Winlevi® inhibits androgen receptors⁵ in the skin and reduces production of sebum and inflammation. Additionally, Winlevi® is rapidly metabolized in the skin, limiting systemic absorption^{6,7}.

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

References:

1. Leyden JJ, Del Rosso JQ, Baum EW. The use of isotretinoin in the treatment of acne vulgaris: clinical considerations and future directions. *J Clin Aesthet Dermatol.* 2014;7(2 Suppl): S3-S21
2. Elsaie ML. Hormonal treatment of acne vulgaris: an update. *Clin Cosmet Investig Dermatol.* 2016;9:241-248
3. Rosette C, Agan FJ, Mazzetti A, Moro L, Gerloni M. Cortexolone 17 α -propionate (clascoterone) is a novel androgen receptor antagonist that inhibits production of lipids and inflammatory cytokines from sebocytes in vitro. *J Drugs Dermatol.* 2019;18(5):412-418
4. Del Rosso JQ, Kircik LH, Stein Gold L, et al. Androgens, androgen receptors, and the skin: from the laboratory to the clinic with emphasis on clinical and therapeutic implications. *J Drugs Dermatol.* 2020;19(3):30-35

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5. WINLEVI® PI + Rosette C, Agan FJ, Mazzetti A, Moro L, Gerloni M. Cortisolone 17 α -propionate (clascoterone) is a novel androgen receptor antagonist that inhibits production of lipids and inflammatory cytokines from sebocytes in vitro. J Drugs Dermatol. 2019;18(5):412-418
6. Mazzetti A, Moro L, Gerloni M, Cartwright M. A phase 2b, randomized, double-blind vehicle controlled, dose escalation study evaluating clascoterone 0.1%, 0.5%, and 1% topical cream in subjects with facial acne. J Drugs Dermatol. 2019;18(6):570.
7. Ferraboschi P, Legnani L, Giuseppe C, Moro L, Ragonesi L, Colombo D. A full conformational characterization of antiandrogen cortisolone- 17 α -propionate and related compounds through theoretical calculations and nuclear magnetic resonance spectroscopy. Med Chem Commun. 2014;5:904-914

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About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050):

Sun Pharma is the world’s fourth largest specialty generics company with presence in Specialty, Generics and Consumer Healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the US as well as Global Emerging Markets. Sun’s high growth Global Specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 16% of company sales. The company’s vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multi-cultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on “X” @SunPharma_Live

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