



Cosmo Pharmaceuticals announces approval of Winlevi® in Australia

Dublin, Ireland – 19 March 2024: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“Cosmo”) reported today that its partner Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) (“Sun Pharma”) 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.

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”.*

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”.*

Please see [here](#) Sun Pharma’s full media release.

Winlevi® will be available in Australia as of June 2024. 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.

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®/ Relafalk® 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 www.cosmopharma.com.

Upcoming Calendar of Events

Full Year Results 2023	March 20, 2024
Investor Day, Zurich	March 20, 2024
Annual General Meeting 2024	May 24, 2024
ODDO BHF Nextcap Forum 2024	June 6, 2024
Half Year Results 2024	July 25, 2024



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
5. WINLEVI® PI + 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
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 cortexolone- 17 α -propionate and related compounds through theoretical calculations and nuclear magnetic resonance spectroscopy. *Med Chem Commun*. 2014;5:904-914

Contact

Hazel Winchester
Head of Investor Relations
Cosmo Pharmaceuticals N.V.
Tel: +353 1 817 03 70
hwinchester@cosmopharma.com

Disclaimer

Some of the statements in this press release may be forward-looking statements or statements of future expectations based on currently available information. Such statements are naturally subject to risks and uncertainties. Factors such as the development of general economic conditions, future market conditions, unusual catastrophic loss events, changes in the capital markets and other circumstances may cause the actual events or results to be materially different from those anticipated by such statements. Cosmo does not make any representation or warranty, express or implied, as to the accuracy, completeness or updated status of such statements. Therefore, in no case whatsoever will Cosmo and its affiliate companies be liable to anyone for any decision made or action taken in conjunction with the information and/or statements in this press release or for any related damages.