



Cosmo Pharmaceuticals announces approval of Winlevi® in Canada

Dublin, Ireland – 20 June 2023: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“Cosmo”) today announced that its partner Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) (“Sun Pharma”) has received marketing authorization (“Notice of Compliance”) from Health Canada for Winlevi® (clascoterone cream 1%). Winlevi® is the first and only androgen receptor inhibitor indicated for the topical treatment of acne vulgaris (acne) in patients 12 years of age and older, and the newest Health Canada-approved formulation to target the hormonal component of acne for Canadian patients in 40 years.

Diana Harbort, President of the Dermatology Division of Cosmo, said: *“We are very pleased with this success our partner Sun Pharma achieved once again with Winlevi®. This is another major achievement in the mission of Cosmo and Sun Pharma to improve the lives of patients affected by skin conditions”.*

As stated by Abhay Gandhi, North America CEO of Sun Pharma: *“We are thrilled to provide a new topical treatment option for the millions of Canadians affected by acne.”*

Please click this [link](#) to read Sun Pharma’s full press release.

Acne is a highly prevalent dermatological condition, affecting approximately 20 per cent of Canadians. Data shows that acne affects patients’ health-related quality of life and may increase the risk of depression and anxiety.

Winlevi® will be available in Canada this Fall. For more information visit www.sunpharma.com/canada.

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 follicles.

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

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 receptors in the skin and reduces production of sebum and inflammation. Additionally, Winlevi® is rapidly metabolized in the skin, limiting systemic absorption.

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**

Half Year Results 2023

Investor Access, Paris

Jefferies London Healthcare Conference 2023

CF&B Communication European Midcap Event, Geneva

July 26, 2023

October 9-10, 2023

November 14-16, 2023

December 1-2, 2023

Disclaimer

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