



Cosmo announces submission of Winlevi® to the European Medicines Agency (EMA)

- *Submission to EMA is supported and based on the efficacy and safety evidence gathered in two identical, randomized, placebo-controlled phase III clinical trials enrolling >1,400 patients with acne vulgaris.*
- *The trials were successful and Winlevi® met the three co-primary endpoints, demonstrating treatment success in Investigator's Global Assessment (IGA) and reductions in acne inflammatory and non-inflammatory lesion count.*
- *Winlevi® was well tolerated and showed a benign safety profile.*
- *FDA approved Winlevi® in 2020, as a novel drug with a unique mechanism of action for the topical treatment of acne in patients aged 12 years and older.*
- *This filing marks a significant milestone in pipeline progression, as approval will open the substantial EU market to already selected, high-standing partners.*

Dublin, Ireland – 10 October 2023: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) ("Cosmo"), a leading pharmaceutical company dedicated to enhancing the lives of individuals suffering from acne, is delighted to announce a pivotal step forward in its mission. Cosmo has officially submitted the Marketing Authorisation Application (MAA) for its innovative acne treatment clascoterone 1% cream (Winlevi®) to the European Medicine Agency (EMA) through the centralized procedure, aimed at obtaining a single Marketing Authorization for the product in the European Union.

Cosmo's decision to submit Winlevi® to the EMA aligns with the Company's dedication to meeting the highest regulatory standards, ensuring that Winlevi® is safe and effective for acne patients. The EMA's rigorous evaluation process will assess the product's safety, quality, and efficacy, ultimately determining its suitability for approval within the European market.

Winlevi®, a first in class topical acne treatment, has been at the forefront of Cosmo's commitment to providing effective solutions for those patients struggling with acne-related skin concerns. The submission to the EMA represents a significant achievement in the Company's journey to bring this safe and effective product, with novel mechanism of action to individuals in need thereof throughout Europe.

Winlevi® has been approved by the United States Food & Drug Administration (FDA) as a novel drug with a unique mechanism of action for the topical treatment of acne in patients aged 12 years and older. It is the first-in-class topical androgen receptor inhibitor that tackles the androgen hormone component of acne and is the first new mechanism of action in acne approved by the FDA since 1982. Winlevi® was launched in the US in November 2021 by Sun Pharma and quickly became the most prescribed branded topical acne drug in the US based on IQVIA data. Over 15,500 US health care providers have prescribed Winlevi® to date, which represents 93% of total health care providers in dermatology. According to the prescriptions generated, Winlevi® has been one of the most successful US launches in the topical acne space in the last 15 years.

Diana Harbort, President of Cosmo's Dermatology Division, said: *"We are very pleased and excited about the potential that Winlevi® holds for acne sufferers in Europe. This submission to the EMA is a pivotal step forward in our mission as well as a testament to our ongoing commitment to innovation. It has also further strengthened our belief in the positive impact that Winlevi® can have on the lives of those struggling with acne in Europe."*

About Cosmo

Cosmo is a pharmaceutical company focused on developing and commercializing 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® 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 the Company's website: www.cosmopharma.com.

Upcoming Calendar of Events

Investor Access, Paris	October 9-10, 2023
Jefferies London Healthcare Conference 2023	November 14-16, 2023
CF&B Communication European Midcap Event, Geneva	December 5, 2023

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