Cosmo Pharmaceuticals announces regulatory approval of Winlevi® in South Korea

Dublin, Ireland – October 7, 2025: Cosmo Pharmaceuticals N.V. (SIX: COPN), a global leader in AI-driven healthcare and specialty pharmaceuticals, today announced that the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea has approved Winlevi® (clascoterone) cream 1% for the treatment of acne vulgaris in patients aged twelve years and older. This approval marks another important milestone in Cosmo's global dermatology expansion and reinforces the Company's commitment to delivering innovative, patient-centric therapies.

Winlevi® is the first topical acne therapy in more than 40 years with a first-in-class mechanism of action. Its active ingredient, clascoterone, is the first commercially available topical androgen-receptor inhibitor acting locally in the sebaceous glands to reduce sebum production and inflammation without systemic anti-androgen effects, supporting safe use in both males and females.

Acne vulgaris is among the most common skin conditions worldwide, affecting over 90 percent of people at some point in their lives and often leading to both physical and emotional consequences, including reduced self-esteem and quality of life. Conventional topical therapies can cause irritation or limited tolerability, and few options directly target the hormonal component of acne. Winlevi® introduces a novel, well-tolerated topical alternative suitable for both male and female patients in South Korea.

Under the June 2023 license agreement, **Hyundai Pharm Co., Ltd.** holds exclusive rights to register and commercialize Winlevi® in South Korea, with Cosmo serving as exclusive product supplier. This collaboration combines Cosmo's proprietary science and global manufacturing with Hyundai Pharm's local dermatology expertise to broaden patient access to advanced acne care.

Giovanni Di Napoli, Chief Executive Officer of Cosmo Pharmaceuticals, commented: *"Approval of Winlevi® in South Korea is a meaningful milestone in our dermatology global expansion and further evidence that we are executing against our 2030 Vision by driving sustainable growth through innovation and focused geographic scale-up. With its novel mechanism and strong safety profile, Winlevi® offers dermatologists and patients in South Korea a differentiated option in acne care."*

Global footprint: Winlevi® is now approved in ten countries: the United States, Canada, Australia, the United Kingdom, New Zealand, Jordan, Singapore, Malaysia, Mexico, and the Republic of Korea. Additional registrations are progressing as Cosmo and its commercial partners continue to expand commercial access to this innovative acne therapy globally.

About Cosmo

Cosmo is a life sciences company focused on MedTech AI, dermatology, gastrointestinal diseases, and contract development and manufacturing (CDMO). We design, develop, and manufacture advanced solutions that address critical medical needs and raise the standard of care. Our technologies are trusted by leading global pharmaceutical and MedTech companies and reach patients and healthcare providers around the world. Guided by our purpose - Building Health Confidence - our mission is to empower patients, healthcare professionals,

and partners by innovating at the intersection of science and technology. Founded in 1997, Cosmo is headquartered in Dublin, Ireland, with offices in San Diego (USA), and in Lainate, Rome, and Catania (Italy). For more information, visit www.cosmohealthconfidence.com

Financial calendar

Jefferies Global Healthcare Conference, London, United Kingdom	November 17-20, 2025
ODDO BHF Forum, Lyon, France	January 8-9, 2026

For further information, please contact:

investor.relations@cosmohc.com