



Cosmo and Hikma Sign License Agreement for Winlevi® in 17 Middle Eastern and North African Countries

Dublin, Ireland – 02 October 2023: Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“Cosmo”) and Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (“Hikma”) today announced the signing of a license agreement for Winlevi® (clascoterone) cream 1% in the Middle East and North Africa (MENA) region (Kingdom of Saudi Arabia, Jordan, Egypt, Morocco, Algeria, Tunisia, Sudan, Iraq, Lebanon, United Arab Emirates, Qatar, Kuwait, Oman, Bahrain, Yemen, Libya, and Syria).

Under the terms of the agreement, Hikma will receive from Cassiopea, a subsidiary of Cosmo, the exclusive right to register and commercialize Winlevi® in 17 Middle Eastern and North African countries. Cassiopea will receive an upfront payment of USD 750,000 in addition to potential regulatory and sales milestones. Cassiopea will be the exclusive supplier of the product at a price calculated on the net sales.

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 15,000 US health care providers have prescribed Winlevi® to date which represents 88% 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.

Acne is considered one of the most prevalent skin conditions in the MENA region due to its predominantly young population, with approximately 55% of the population under the age of 30¹. This agreement grants Hikma exclusive rights to commercialize Winlevi® in MENA markets, including Saudi Arabia, Egypt and UAE, which represent about 75% of the total acne market in MENA².

Hikma is the third largest pharmaceutical company in MENA. Having operated in the region for more than 40 years, it has deep-rooted expertise, an extensive local manufacturing footprint as well as a strong and experienced salesforce of approximately 2,000 people. Hikma demonstrates strong performance in the dermatology market in the MENA region and is ranked among the top 10 companies in this therapeutic area.

Diana Harbort, President of Cosmo’s Dermatology Division, said: *“We are delighted to partner with Hikma. Their significant experience in commercialization in the MENA region gives us great confidence in their ability to successfully register and market Winlevi®. We look forward to more acne patients around the globe having access to Winlevi®.”*

Mazen Darwazah, Hikma’s Executive Vice Chairman and President of MENA, said: *“We are excited to partner with Cosmo to bring this novel dermatological treatment to our patients in MENA. Winlevi® has a unique method of action in which it can target the acne hormones in the skin. This agreement strengthens our dermatology portfolio, a key therapeutic area for Hikma. It also enables us to increase patients’ access to differentiated medicines in the region putting better health within reach. We look forward to working with Cosmo.”*



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.

About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P and BBB-/positive Fitch). Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle-East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,800 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com.

Upcoming Calendar of Events

Investor Access, Paris

Jefferies London Healthcare Conference 2023

CF&B Communication European Midcap Event, Geneva

October 9-10, 2023

November 14-16, 2023

December 5, 2023

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¹ Youth at the Centre of Government Action, A Review of the Middle East and North Africa; Jun 2022.

² IQVIA data MAT Aug 2023.

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