

GENERAL ANNOUNCEMENT::HYPHENS PHARMA LICENSES WINLEVI FOR ALL 10 ASEAN COUNTRIES FROM COSMO PHARMACEUTICALS

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Submitted By (Co./ Ind. Name)

Lim See Wah

Designation

Executive Chairman and CEO

Description (Please provide a detailed description of the event in the box below)

Please refer to attached press release.

This announcement has been reviewed by the Company's Sponsor, SAC Capital Private Limited (the "Sponsor"). It has not been examined or approved by the Singapore Exchange Securities Trading Limited (the "SGX-ST") and the SGX-ST assumes no responsibility for the contents of this announcement including the correctness of any statements or opinions made or reports contained in this announcement.

The contact person for the Sponsor is Ms Lee Khai Yinn (Tel: +65 6232 3210) at 1 Robinson Road, #21-00 AIA Tower, Singapore 048542.

Attachments

[Hyphens - Winlevi Licensing.pdf](#)

Total size =273K MB



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Media Release

Hyphens Pharma licenses Winlevi® for all 10 ASEAN countries from Cosmo Pharmaceuticals

- **Winlevi® is a first-in-class topical drug for the treatment of acne approved by U.S. FDA in August 2020.**
- **It will reinforce our Proprietary Brand segment’s dermatological franchise.**

Singapore, 21 December 2022 – Hyphens Pharma International Limited (“**Hyphens Pharma**”, “**凯帆药剂国际有限公司**”, or the “**Company**”, and together with its subsidiaries, the “**Group**”), Singapore’s leading specialty pharmaceutical and consumer healthcare group, is pleased to announce that its subsidiary, Hyphens Pharma Pte. Ltd., has entered into exclusive license and supply agreements with Cassiopea S.p.A., a subsidiary of Cosmo Pharmaceuticals N.V. (SIX: COPN, XETRA: C43) (“**Cosmo**”) for the exclusive rights to develop and commercialize Winlevi® (clascoterone) cream 1% and all future product extension and/or improvement in the treatment of acne in 10 countries across Southeast Asia.

Winlevi® (www.winlevi.com) is a U.S. Food & Drug Administration (“**FDA**”) approved 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 type of acne medication approved by the FDA since 1982. As the only topical cream to treat hormonal acne directly in the skin, it offers a non-antibiotic approach for acne-sufferers everywhere. Winlevi® inhibits sebum production and inflammation by targeting the androgen receptors in the sebaceous gland cells. Oral treatments are typically prescribed to address hormonal acne, but usually only prescribed to females. With Winlevi®, males suffering from acne, as well as females who don’t want to take oral medications,

can now benefit from this first-in-class treatment, making Winlevi® a game-changer in the fight against acne.

Launched in the U.S. in November 2021, Winlevi® is already the most prescribed branded topical acne drug in the U.S. based on IQVIA data. Over 12,000 U.S. physicians have prescribed Winlevi® to date. According to the prescriptions generated, Winlevi® has been one of the most successful U.S. launches in the topical acne space in the last 15 years.

In a study involving 3,888 Singapore Chinese subjects, the estimated prevalence of acne vulgaris is 53.8%¹. Acne can have profound social and psychological effects on adolescents or young adults when it affects their self-esteem². As the first novel acne drug in decades, Winlevi® has huge potential to revolutionize the acne treatment space. Winlevi® will be Hyphens Pharma's first innovative therapeutics, deepening its dermatology pipeline.

Today, Hyphens Pharma has a proprietary range of dermatological products for acne, atopic dermatitis, hyperpigmentation, and hair loss. These are available through doctors including dermatologists, paediatricians, and general practitioners as well as major retail pharmacies.

Diana Harbort, President of Cosmo's Dermatology Division, said: *"We are very pleased to partner with Hyphens Pharma. Their strong expertise in Southeast Asia gives us great confidence in their ability to gain regulatory approval and commercialise Winlevi® in the region. The success of Winlevi® in the U.S. has given us the opportunity to select the best partners in each region and to eventually make the product available to more patients around the globe."*

Lim See Wah, Executive Chairman and CEO of Hyphens Pharma, said: *"Acne is a medical condition that affects millions in the ASEAN region. Yet, the medical management of acne*

¹ Heng AHS et al. Epidemiological Risk Factors Associated with Acne Vulgaris Presentation, Severity, and Scarring in a Singapore Chinese Population: A Cross-Sectional Study. *Dermatology*. 2022;238(2):226-235.

² Moosa AS et al. Primary care approach to managing acne. *Singapore Med J*. 2021 Nov;62(11):568-573.

remained largely similar due to the absence of new drugs. Winlevi® is the first new class of topical drug for the treatment of acne that is approved by U.S. FDA in nearly 40 years. We are thus very proud to be able to bring Winlevi® to doctors and patients in the entire ASEAN region. We would like to thank Cosmo for this partnership and their confidence in Hyphens Pharma. This deal also affirms Hyphens Pharma's strength as ASEAN's leading specialty pharmaceutical company with a strong focus on skin health. We will continue to innovate, as well as to bring to market relevant innovations from the world to our region, so as to continue serving our doctors and patients."

Pursuant to the exclusive license and supply agreements, the Group will pay Cassiopea S.p.A., an upfront payment of US\$1 million, potential regulatory and sales milestones totalling up to US\$4 million and customary double-digit royalties on net sales. The exclusive license and supply agreements will not have a material effect on the net tangible assets or earnings per share of the Group for the financial years ending 31 December 2022 and 31 December 2023.

End.

About Hyphens Pharma International Limited (<http://www.hyphensgroup.com>)

Hyphens Pharma International Limited and its subsidiaries (the "Group") is Singapore's leading specialty pharmaceutical and consumer healthcare group, leveraging on its diverse footprint in ASEAN countries. The Group has a direct presence in Singapore, Vietnam, Malaysia, Indonesia and the Philippines, and is supplemented by a marketing and distribution network covering 10 other markets – Bangladesh, Brunei, Cambodia, China, Hong Kong S.A.R., Macau S.A.R., Myanmar, Oman, South Korea and Sri Lanka.

Singapore is the Group's regional headquarters, where its strategic planning, finance, regulatory affairs, research and development, legal, business development and logistics operations are based. The Group's core business comprises the following segments: Specialty Pharma Principals, Proprietary Brands, and Medical Hypermart & Digital. Besides marketing and selling a range of specialty pharmaceutical products in selected ASEAN countries through exclusive distributorship or licensing and supply agreements with brand principals mainly from Europe and the United States, the Group also develops, markets and sells its own proprietary range of dermatological products and health supplement products. In addition, the Group operates a medical hypermart for healthcare professionals, healthcare institutions and retail pharmacies, to supply pharmaceutical products and medical supplies and an online pharmacy for doctors to prescribe and have medications delivered to their patients' homes.

About Cosmo N.V.

(<https://www.cosmopharma.com>)

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.

Issued on behalf of : **Hyphens Pharma International Limited**
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