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Zhaoke Ophthalmology Limited
兆科眼科有限公司
(Incorporated in the British Virgin Islands with limited liability and continued in the Cayman Islands)
(Stock Code: 6622)

VOLUNTARY ANNOUNCEMENT – FDA CLEARANCE OF IND APPLICATION FOR CsA OPHTHALMIC GEL

This announcement is made by the board of directors (the "**Board**") of Zhaoke Ophthalmology Limited (the "**Company**") on a voluntary basis.

The Board of the Company is pleased to announce that the U.S. Food and Drug Administration ("**FDA**") has cleared the Company's Investigational New Drug ("**IND**") application for Cyclosporine (CsA) Ophthalmic Gel, one of the Company's core products, for the treatment of moderate-to-severe dry eye disease ("**DED**"). The upcoming study is set to be a Phase III, multicenter, randomized, double-masked, active-controlled study.

Based on comprehensive scientific communication and discussions with the FDA, the Company has aligned with the FDA to incorporate data from the completed pivotal Phase III clinical trial (COSMO study) as well as the ongoing Phase III trial in China into its U.S. development plan.

ABOUT CsA OPHTHALMIC GEL

CsA Ophthalmic Gel is an innovative cyclosporine gel being developed by the Company in China for the treatment of moderate to severe DED. Unlike Restasis®, emulsion formulation, CsA Ophthalmic Gel is a proprietary hydrogel with patent approval in China and internationally. This novel formulation enhances the pharmacokinetic profiles and exposure of CsA on the ocular surface, giving CsA more time to exert its effect on DED.

In fact, the previous phase II study results suggested that 0.05% CsA Ophthalmic Gel (q.d.), applied once daily at night, had efficacy and safety profiles at least similar to those of Restasis® (0.05% CsA, b.i.d.) which is applied twice daily. This effectively eliminates the need for daytime administration and the associated discomfort and inconvenience. In addition,

the results of the previous phase III study (COSMO) conducted by the Company indicate that the onset of action for CsA Ophthalmic Gel can start in as early as two weeks. As a result of once daily application and a rapid onset of action, the Company expects its CsA Ophthalmic Gel to significantly improve patients' compliance and quality of life.

Cautionary statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that it will ultimately commercialize CsA Ophthalmic Gel successfully. Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
Zhaoke Ophthalmology Limited
Dr. Li Xiaoyi
Chairman

Hong Kong, June 4, 2025

As at the date of this announcement, the Board comprises Dr. Li Xiaoyi and Mr. Dai Xiangrong as executive Directors; Ms. Leelalertsuphakun Wanee and Ms. Tiantian Zhang as non-executive Directors; and Mr. Wong Hin Wing, Prof. Lo Yuk Lam and Mr. Liew Fui Kiang as independent non-executive Directors.