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 — APPROVAL OF INVESTIGATIONAL NEW DRUG APPLICATION FOR PHASE III CLINICAL TRIAL OF CYCLOSPORINE A (CsA) OPHTHALMIC GEL BY NMPA AND COMPLETION OF NVK002 PHASE III CHINA-CHAMP LAST PATIENT LAST VISIT IN CHINA

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 Company's Investigational New Drug ("**IND**") application of Cyclosporine A (CsA) Ophthalmic Gel for the treatment of moderate to severe dry eye disease ("**DED**") has been approved by the National Medical Products Administration (the "**NMPA**") of China. This Phase III clinical trial was designed based on the requirements outlined in the Technical Guidelines on Clinical Trials for Therapeutic Drugs for Dry Eyes issued by the Center for Drug Evaluation in September 2023.

The Board of the Company is pleased to announce that the last patient last visit was completed for the two-year Phase III clinical trial ("**China CHAMP**") of one of the Company's core products, NVK002, for the treatment of myopia, on August 5, 2024. The main objective of China CHAMP is to evaluate the efficacy and safety of NVK002 (low dose atropine 0.01% and 0.02%) in the treatment of myopia progression in children and adolescents in the Chinese population. This trial involved 18 centers and enrolled 777 patients.

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.

ABOUT DRY EYE DISEASE

DED is a complex multifactorial ocular surface disease involving inflammation and associated with different symptoms. It is one of the most common eye diseases in China and globally. According to China Insights Industry Consultancy Limited, the market size of DED drugs in China is forecasted to increase from US$430 million in 2019 to US$6.7 billion in 2030, at a compound annual growth rate of 28.4%. The number of DED patients in China is expected to grow from 214 million in 2019 to 266 million in 2030 with the diagnosis rate expected to increase from 11.5% in 2019 to 33.4% in 2030. Meanwhile, the number of DED patients in the United States is expected to grow from approximately 20 million in 2019 to approximately 28 million in 2030 with the diagnosis rate expected to increase from 47.4% in 2019 to 65.2% in 2030.

ABOUT NVK002

NVK002 is an investigational novel topical ophthalmic solution to control myopia progression in children and adolescents. NVK002 has a proprietary formulation that successfully addresses the instability of low-concentration atropine, this technology has intellectual property protection globally. It is preservative-free with an expected shelf life of over 24 months. According to information from China Insights Consultancy ("**CIC**"), NVK002 is currently one of the most advanced atropine drug candidates globally for treating myopia progression, and targets the broadest patient group, covering children and adolescents from 3 to 17 years old.

The clinical development of NVK002 involves two different concentrations of atropine to allow flexibility in achieving maximal efficacy and minimal adverse effects for tailoring to the needs of individual patients.

ABOUT MYOPIA PROGRESSION CONTROL

Myopia has become a major social issue that plagues the growth of children and adolescents in China. In the "14th Five-Year National Health Plan" issued by the State Council of the Chinese government, clear instructions have been made for the prevention and treatment of myopia in children and adolescents, and reduction of the overall myopia rate among children and adolescents nationwide by more than 0.5% per year. The Ministry of Education also issued the "Proposal for Parents of Comprehensive Prevention and Control of Myopia in Children and Adolescents", calling on parents to pay attention to their children's eye health.

According to the World Health Organization and CIC, currently there are approximately 700 million myopia patients in China, among them, 163 million are children and adolescents, who may be able to benefit from NVK002. The Board believes the potential commercialization of NVK002 will allow the Company to establish a leading position in meeting these huge unmet needs in China.

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 and NVK002 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, August 10, 2024

As at the date of this announcement, the Board of the Company 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.