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 – U.S. FDA ACCEPTANCE OF NEW DRUG APPLICATION FOR NVK002 FOR TREATMENT OF MYOPIA PROGRESSION

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 partner – Vyluma Inc. ("**Vyluma**") has announced that the U.S. Food and Drug Administration ("**FDA**") has accepted for review the New Drug Application ("**NDA**") for its lead compound, NVK002 (low dose atropine 0.01%) as a potential treatment for myopia in children. NVK002 is a proprietary, investigational, preservative-free eye drop administered nightly and intended for patients ages 3 to 17. A Prescription Drug User Fee Act (PDUFA) goal date of January 31, 2024, has been assigned by FDA.

Vyluma's NDA is supported by positive results from its landmark, three-year, placebo-controlled international Phase III CHAMP (Childhood Atropine for Myopia Progression) clinical study, evaluating the safety and efficacy of NVK002 in nearly 600 children. NVK002 at a dose of 0.01% achieved statistically significant and clinically meaningful differences from placebo at month 36 in the key outcome measures of responder analysis, mean change from baseline in Spherical Equivalent Refraction (SER), and mean change from baseline in axial length. NVK002 demonstrated strong safety and tolerability when compared to placebo with no serious ocular adverse events reported.

The results of the CHAMP trial were published on June 1, 2023, in JAMA Ophthalmology, a monthly peer-reviewed medical journal covering all aspects of ophthalmology and published by the American Medical Association.

In China, the Company has been conducting two parallel Phase III clinical trials: the two-year Phase III clinical trial ("**China CHAMP**") and the concurrent one-year Phase III bridging clinical trial ("**Mini-CHAMP**"). The patient enrollment was completed for China CHAMP and Mini-CHAMP on July 21, 2022 and July 28, 2022 respectively, which is 2 months ahead of schedule and 3 months ahead of schedule respectively. Reference is made to the announcement of the Company dated August 2, 2022 in relation to the patient enrollment completion for Phase III clinical trials of NVK002 for the treatment of myopia progression.

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.

ABOUT CHAMP

Phase III CHAMP is a three-arm, randomized, multi-center, double-masked, placebo-controlled study conducted across the United States and Europe in nearly 600 children and adolescents aged three to seventeen years at enrollment. The study consists of two stages: a three-year treatment period to evaluate the safety and efficacy of NVK002, after which enrolled patients were re-randomized for a masked, one-year treatment period to characterize cessation of therapy.

ABOUT THE LICENSE AGREEMENT WITH VYLUMA INC.

In October 2020, the Company entered into a license agreement, namely the NVK002 License Agreement, with Nevakar Inc., which later assigned the agreement to its wholly-owned subsidiary, Vyluma Inc. for an exclusive license to develop, manufacture, register, import and commercialize NVK002 in Greater China, South Korea and certain countries in Southeast Asia (including Brunei, Burma, Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand and Vietnam). For details of the license agreement in relation to NVK002, please refer to "Business – Collaboration and License Agreements – License of NVK002" of the prospectus of the Company dated April 16, 2021.

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 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, June 7, 2023

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