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 – POSITIVE TOP-LINE RESULTS FROM NVK002 ONE-YEAR PHASE III CLINICAL TRIAL (MINI-CHAMP) IN CHINA FOR THE TREATMENT OF MYOPIA PROGRESSION IN CHILDREN

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 the top-line results from its one-year Phase III clinical trial ("**Mini-CHAMP**") of one of the Company's core products, NVK002. Analysis of this multi-center study, performed after one year of treatment, demonstrates strong safety and efficacy for NVK002 as a potential treatment for the progression of myopia in children, and indicates consistent trends with the Phase III CHAMP clinical study performed by the Company's US partner, Vyluma Inc. ("**Vyluma**") during its first year.

Phase III Mini-CHAMP is a randomized, double-masked, placebo-controlled, multi-center clinical study. The main objective is to evaluate the efficacy and safety of NVK002 in slowing the progression of myopia in children and adolescents in China. The trial involved 16 centers and enrolled 526 children and adolescents, co-led by Professor Qu Xiao Mei from Eye and ENT Hospital of Fudan University and Professor Yang Xiao from Zhongshan Ophthalmic Center, Sun Yat-Sen University as the Principal Investigators.

The study consists of two stages: a one-year treatment period to evaluate the safety and efficacy of NVK002, after which enrolled patients are re-randomized for a masked, one-year treatment period to characterize cessation of therapy.

Mini-CHAMP successfully met its primary efficacy endpoint with both doses of 0.01% and 0.02% NVK002 achieving statistically and clinically meaningful differences versus placebo in terms of slowing myopia progress in the study population.

NVK002 at both doses were well tolerated and safe as reflected by the low treatment discontinuation rates and low ocular serious adverse events (SAEs) respectively.

The Company plans to communicate with regulatory authorities to advance the process of New Drug Application ("**NDA**") for NVK002 in China combining the results from Mini-CHAMP with Vyluma's data from Phase III CHAMP study.

The Company has been conducting a parallel two-year Phase III clinical trial ("**China CHAMP**"). The China CHAMP trial involved 18 centers and enrolled 777 patients. Patient enrollment was completed on July 21, 2022.

On October 11, 2023, Vyluma announced positive top-line results from the second stage of its Phase III CHAMP clinical study NVK002. Analysis of the results of this multi-center, international study conducted after four years of treatment and follow up, show continued strong safety, the absence of rebound upon washout of the study drug, and continued efficacy for NVK002 as a potential treatment for myopia in children.

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 at least 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 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 develop and market NVK002 successfully. Shareholders of the Company and potential investors are advised to exercise caution when dealing with the shares of the Company.

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

Hong Kong, October 13, 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.