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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 – FIRST PATIENT ENROLLED FOR NVK002 PHASE III BRIDGING CLINICAL TRIAL (MINI-CHAMP) 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 first patient was enrolled in the one-year Phase III bridging clinical trial ("**Mini-CHAMP**") of one of the Company's core products, NVK002, on May 13, 2022. Earlier in March 2022, the Company has announced the first patient enrollment for the concurrent two-year Phase III clinical trial ("**China CHAMP**"), and as of May 16, 2022, China CHAMP has successfully enrolled 144 patients and is continuing the recruitment process.

The main objective of the China CHAMP and Mini-CHAMP is to evaluate the efficacy and safety of NVK002 in myopia progression control of children and adolescents. The China CHAMP trial will involve 19 centers and enroll 777 patients, led by Professor Wang Ning Li from Beijing Tongren Hospital as the Principal Investigator. The Mini-CHAMP trial will involve 18 centers and enroll 526 patients, 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.

China CHAMP and Mini-CHAMP have enrolled a total of 150 patients in China as of May 16, 2022. Together with Vyluma Inc.'s ("**Vyluma**") clinical study in the United States and Europe, the overall CHAMP trial will have the largest number of patients enrolled on a combined basis amongst all atropine program clinical trials globally, and with the longest and most comprehensive set of data on safety and efficacy.

The CHAMP trial of NVK002 of the Company's partner – Vyluma (a wholly owned subsidiary of Nevakar Inc. ("**Nevakar**") established in May 2021) in the United States and Europe is the most advanced study for drug registration of low dose atropine for slowing the progression of myopia in children and adolescents in the world. The CHAMP trial with three years of NVK002 treatment is expected to complete before the end of 2022. A New Drug Application submission to the United States Food and Drug Administration (the "FDA") is expected in 2023 and NVK002 is currently positioned as the first approved product for slowing the progression of myopia in the world. If it is approved by the FDA in the United States, the drug will also be eligible for real world study in the Hainan Province of China.

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 myopia progression control, 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.

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.

In October 2020, the Company entered into a license agreement, namely the NVK002 License Agreement, with Nevakar, which later assigned the agreement to its wholly-owned subsidiary, Vyluma 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, May 19, 2022

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, Ms. Tiantian Zhang, Ms. Cai Li and Mr. Chen Yu as non-executive Directors; and Mr. Wong Hin Wing and Prof. Lo Yuk Lam as independent non-executive Directors.