

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 – PATIENT ENROLLMENT
COMPLETE FOR PHASE III CLINICAL TRIALS OF 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 patient enrollment was completed for the two-year Phase III clinical trial (“**China CHAMP**”) and the concurrent one-year Phase III bridging clinical trial (“**Mini-CHAMP**”) of one of the Company’s core products, NVK002, on July 21, 2022 and July 28, 2022 respectively.

The main objective of the China CHAMP and Mini-CHAMP is to evaluate the efficacy and safety of NVK002 in the treatment of myopia progression in children and adolescents. Led by Professor Wang Ning Li from Beijing Tongren Hospital as the Principal Investigator, the China CHAMP trial involves 19 centers and has completed the enrollment of 777 patients in less than 4 months and is 2 months ahead of schedule. 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 Mini-CHAMP trial involves 18 centers and has completed the enrollment of 526 patients in less than 3 months and is 3 months ahead of schedule. Completion of the enrollment of these two Phase III trials puts the Company at the forefront in the development of drug treatment for myopia progression in China.

In the United States and Europe, the Company’s partner, Vyluma Inc, has been conducting parallel Phase III clinical trial – CHAMP – with three years of NVK002 treatment which is expected to complete before the end of 2022. A New Drug Application (“**NDA**”) submission to the US Food and Drug Administration (the “**FDA**”) is expected in 2023 and NVK002 is currently positioned as the first clinically-proven pharmaceutical product approved for treating the progression of myopia in the world.

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.

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, August 2, 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, Prof. Lo Yuk Lam and Mr. Liew Fui Kiang as independent non-executive Directors.