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 – UPDATES ON PHASE III CLINICAL TRIALS FOR TAB014 AND EPINASTINE HCl AND UPDATE ON THE NEW DRUG APPLICATION FOR CYCLOSPORINE A (CsA) OPHTHALMIC GEL

This announcement is made by the board of directors (the "**Board**") of Zhaoke Ophthalmology Limited (the "**Company**") on a voluntary basis.

UPDATES ON PHASE III CLINICAL TRIALS FOR TAB014 AND EPINASTINE HCl

The Board of the Company is pleased to announce that the patient enrollment was completed for the Phase III clinical trial of one of the Company's core drug candidates, TAB014, for the treatment of wet (neovascular) age-related macular degeneration ("**wAMD**"), on September 16, 2023, ahead of schedule.

The patient enrollment was also completed for the Phase III clinical trial of Epinastine HCl targeting allergic conjunctivitis with a dual mechanism of action of anti-histamine and mast cell stabilization, on September 15, 2023. The last patient last visit was completed on September 28, 2023.

The Phase III clinical trial of TAB014 is a randomized, double-blind and non-inferiority study. The main objective of the study is to evaluate the change from baseline in best corrected visual acuity (BCVA) at week 52 in the TAB014-treated subjects group compared with Lucentis®-treated subjects group. The study involved approximately 60 centres and enrolled a total of 488 patients, led by Professor Chen Youxin from Peking Union Medical College Hospital as the Principal Investigator.

The Phase III clinical trial of Epinastine HCl is a multicenter, randomized, double-blind, positive-controlled Phase III clinical study on the efficacy and safety of 0.05% epinastine hydrochloride eye drops in the treatment of patients with seasonal allergic conjunctivitis. The study involved approximately 14 centres and enrolled a total of 266 patients.

UPDATE ON THE NEW DRUG APPLICATION FOR CsA OPHTHALMIC GEL

As disclosed in previous announcements, the Company's New Drug Application ("**NDA**") of CsA Ophthalmic Gel for the treatment of dry eye disease ("**DED**") has been accepted by the Center For Drug Evaluation ("**CDE**") of the National Medical Products Administration ("**NMPA**") on June 8, 2022. It passed the on-site regulatory and clinical trial inspections by the NMPA, and the Good Manufacturing Practice ("**GMP**") conducted by the Guangdong Medical Products Administration in January 2023.

As an update to this application, following several rounds of communication between the Company and regulatory authorities, the Company expects it will require more time than is remaining in the statutory supplementary material process to adequately address the additional questions from the CDE. As such, after prudent considerations and consultations with the CDE, the Company has decided to voluntarily withdraw the application and will resubmit the NDA once the supplementary documentation is complete.

The Company will closely monitor and actively advance the subsequent progress of the NDA, and will make further announcement(s) as and when appropriate.

ABOUT TAB014

TAB014 (recombinant humanized anti-vascular endothelial growth factor ("**VEGF**") monoclonal antibody) is an ophthalmic formulation of bevacizumab being developed for the treatment of wAMD. The main pathological feature of wAMD is choroidal angiogenesis in the macula, with VEGF playing an important role in the angiogenesis process. TAB014 is able to bind specifically to VEGF and block it from binding to its receptors, thereby inhibiting angiogenesis. TAB014 will eventually be administered as an intravitreal injection for the treatment of wAMD.

ABOUT wAMD

wAMD is a leading cause of vision loss and blindness in people over 50 years old in China and globally. According to China Insights Consultancy the market size of wAMD drugs in China is forecast to increase from US$241.5 million to approximately US$3.5 billion from 2019 to 2030, at a CAGR of 27.5%. TAB014 is the first bevacizumab-based antibody under clinical development indicated for wAMD in China, and is expected to be a cost-effective therapy. The clinical research and commercialization project in relation to TAB014 was listed by the Development Center for Medical Science & Technology of the National Health Commission of China as a special major project for technologies of innovative manufacturing of major new drugs at the end of 2019.

ABOUT THE AGREEMENT WITH TOT BIOPHARM Co., Ltd.

In March 2022, the Company announced that Zhaoke (Guangzhou) Ophthalmology Pharmaceutical Limited ("**Zhaoke Guangzhou**"), a wholly-owned subsidiary of the Company and TOT BIOPHARM Co., Ltd. ("**TOT Suzhou**", a wholly-owned subsidiary of TOT BIOPHARM International Company Limited ("**TOT BIOPHARM**"), SEHK: 1875), entered into a supplemental agreement (the "**Current Supplemental Agreement**"), pursuant to which Zhaoke Guangzhou will have full control in the execution of clinical trials and the ultimate decision-making power in the development and commercialization of TAB014 in China, Hong Kong and Macau. Zhaoke Guangzhou is also given the right of developing TAB014 for other ophthalmic indications besides wAMD or novel formulations for ophthalmic indications. TOT Suzhou will continue to be responsible for the manufacturing of TAB014 for clinical trial and commercial purposes.

ABOUT EPINASTINE HCl

Epinastine HCl is an epinastine eye drop for the treatment of allergic conjunctivitis. Epinastine HCl is a candidate with a dual mechanism of action of anti-histamine and mast cell stabilization. It is the first-line therapy for allergic conjunctivitis in China, especially for acute patients. We are developing epinastine HCl as a generic to Elestat, which was developed by Allergan. Our epinastine HCl eye drop is a potential first-to-market generic in China. As the originator drug has never been marketed in China, a clinical trial is required by China's National Medical Products Administration to obtain the first marketing authorization.

ABOUT CsA OPHTHALMIC GEL

CsA Ophthalmic Gel is an innovative cyclosporine gel being developed by the Company in China for the treatment of 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, phase III study results 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.

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 TAB014 and Epinastine HCl 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 3, 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.