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 – CYCLOSPORINE A (CsA) OPHTHALMIC GEL PASSED THE ON-SITE REGULATORY AND CLINICAL TRIAL INSPECTIONS BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION AND THE GMP COMPLIANCE INSPECTION BY THE GUANGDONG MEDICAL PRODUCTS ADMINISTRATION

This announcement is made by the board of directors (the "**Board**") of Zhaoke Ophthalmology Limited (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis.

The Board of the Company is pleased to announce that one of the Company's core drug candidates, Cyclosporine A ("**CsA**") Ophthalmic Gel passed the on-site regulatory and clinical trial inspections by the National Medical Products Administration (the "**NMPA**"). The inspections verified the original records and information on the research and development process of CsA as well as the phase III clinical trial, which was the largest clinical trial conducted in China targeting moderate to severe dry eye disease ("**DED**") to date.

The Company also passed the Good Manufacturing Practice ("**GMP**") conducted by the Guangdong Medical Products Administration. It confirms that the Company has put in place a GMP management framework, a core team, a complete set of analytical instruments, equipment and facilities, a well-managed documentation system and proper operations of the production and quality systems for CsA.

The passing of all three inspections marks a major milestone for the Company towards the final regulatory approval and commercialization of CsA Ophthalmic Gel. In addition, the positive result of the inspections is another validation of the R&D and clinical development capabilities as well as the quality management system of the Company.

On June 8, 2022, the Company's New Drug Application ("**NDA**") of CsA Ophthalmic Gel for DED treatment was accepted for review by the Center for Drug Evaluation ("**CDE**") of the NMPA.

CsA Ophthalmic Gel remains on track to become the Company's first self-developed innovative drug to commercialize in China.

In August 2022, the Company initiated its product coverage of DED with the launch of 堡得视® heat compress eyepatch. This product has been approved in China as a class 2 medical device for reducing symptoms of mild cases of DED.

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.

ABOUT DED

DED is a complex multifactorial ocular surface disease involving inflammation and associated with different symptoms. It is one of the most common eye diseases in China and globally. According to China Insights Industry Consultancy Limited, the market size of DED drugs in China is forecasted to increase from US$430 million in 2019 to US$6.7 billion in 2030, at a compound annual growth rate of 28.4%. The number of DED patients in China is expected to grow from 214 million in 2019 to 266 million in 2030 with the diagnosis rate expected to increase from 11.5% in 2019 to 33.4% in 2030. Meanwhile, the number of DED patients in the United States is expected to grow from approximately 20 million in 2019 to approximately 28 million in 2030 with the diagnosis rate expected to increase from 47.4% in 2019 to 65.2% in 2030.

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

Hong Kong, January 31, 2023

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.