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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)

THE COMPANY'S SELF-DEVELOPED INNOVATIVE DRUG CYCLOSPORINE OPHTHALMIC GEL RECEIVES MARKETING APPROVAL FROM THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

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, based on the Company's Phase III clinical study, COSMO, the Company's self-developed innovative drug Cyclosporine Ophthalmic Gel has received marketing approval from the National Medical Products Administration ("**NMPA**") on 10 November 2026 for the indication to promote tear secretion in patients with dry eye disease, for patients with reduced tear production due to dry eye, to improve their ocular signs.

Cyclosporine Ophthalmic Gel is administered only once daily at bedtime, which avoids ocular discomfort and inconvenience caused by daytime dosing. In addition, clinical efficacy can be observed as early as two weeks after treatment initiation. With its two key advantages of once-daily administration and rapid onset of action, Cyclosporine Ophthalmic Gel is expected to substantially improve patient medication adherence and enhance quality of life.

ABOUT CYCLOSPORINE OPHTHALMIC GEL

Cyclosporine Ophthalmic Gel is an ophthalmic gel formulation self-developed by the Company. It adopts a drug delivery technology that innovatively combines nanomicellar solubilization with an ophthalmic gel. Featuring excellent mucoadhesive properties and solubilizing effects, it can significantly prolong drug residence time on the cornea, enhance the corneal penetration of cyclosporine and improve its bioavailability. Being preservative-free and containing excipients also found in artificial tears, it provides lubrication and protection to the ocular surface while ensuring efficacy, causes minimal ocular irritation and helps improve patients' tolerability of and adherence to long-term treatment.

ABOUT THE PHASE III CLINICAL STUDY COSMO

The Phase III clinical study COSMO is a multicenter, randomized, double-blind, vehicle-controlled study that enrolled 644 patients with moderate-to-severe dry eye disease. Participants were randomly assigned to receive either Cyclosporine Ophthalmic Gel or vehicle control, administered once daily at bedtime. Follow-up assessments were conducted on Days 14, 42, and 84.

On Day 84, 73.7% of patients in the Cyclosporine Ophthalmic Gel group achieved an improvement of ≥1 point from baseline in Inferior Corneal Staining Score ("**ICSS**"), compared with 53.2% in the vehicle control group, demonstrating a statistically significant difference ($P < 0.0001$) and meeting the study's primary endpoint. Notably, a significant treatment difference was observed as early as Day 14 ($P < 0.05$), indicating that Cyclosporine Ophthalmic Gel demonstrated a rapid onset of efficacy within two weeks of treatment initiation.

Beginning on Day 14, patients treated with Cyclosporine Ophthalmic Gel showed statistically significant improvements compared with the vehicle control group in the following measures: mean change from baseline in Inferior Corneal Staining Score ("**ICSS**"), mean change from baseline in Oxford Scale scoring of corneal and conjunctival staining, mean change from baseline in tear production as measured by anesthetized Schirmer tear test. These treatment benefits were sustained through Day 84 (all $P < 0.05$).

The incidence of treatment-related ocular adverse events during the study was 12.5% in the Cyclosporine Ophthalmic Gel group, compared with 5.4% in the vehicle control group. The most frequently reported adverse reaction in the Cyclosporine Ophthalmic Gel group was eye pain (8.1%), while the incidence of all other adverse reactions was below 3%. No drug-related serious adverse events were reported during the study. Overall, Cyclosporine Ophthalmic Gel demonstrated a favorable safety profile and good tolerability.

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 Cyclosporine Ophthalmic Gel 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, 13 November 2026

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 and Ms. Tiantian Zhang as non-executive Directors; and Mr. Wong Hin Wing, Prof. Lo Yuk Lam and Mr. Liew Fui Kiang as independent non-executive Directors.