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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 – ORPHAN DRUG DESIGNATION RECEIVED FROM THE U.S FDA FOR MELPHALAN TARGETING PEDIATRIC RETINOBLASTOMA

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 U.S. Food and Drug Administration ("**FDA**") has granted Orphan Drug Designation ("**ODD**") to its proprietary formulation of melphalan for the treatment of pediatric retinoblastoma ("**RB**"), a rare pediatric eye cancer.

Securing ODD establishes a clear regulatory pathway toward Investigational New Drug ("**IND**") submission in the U.S. More substantially, if Melphalan is successfully developed and approved, the Company would become eligible for seven years of U.S. market exclusivity upon New Drug Application ("**NDA**") approval. This comprehensive protection encompasses marketing authorization holder ("**MAH**") status, data exclusivity, and crucially, prevents FDA approval of any other melphalan-based product for the RB indication during this period – regardless of formulation innovations.

ABOUT MELPHALAN

Melphalan is an alkylating agent that exerts its anticancer activity by reacting with DNA and interfering with DNA replication and cell division. This stops the growth and spread of cancer cells in the body. Currently, Melphalan is given as the conditioning regimen prior to autologous stem cell transplantation in patients with multiple myeloma, or as the palliative treatment of multiple myeloma if oral therapy is not appropriate.

ABOUT PEDIATRIC RETINOBLASTOMA

Pediatric retinoblastoma is a rare eye cancer that primarily affects children under the age of five. In the United States, approximately 200 to 300 cases are diagnosed annually (American Cancer Society, 2023). Globally, the incidence is approximately one in 15,000 to 18,000 live births, resulting in roughly 8,000 to 9,000 new cases each year (World Health Organization, 2024). The overall survival rate exceeds 90% worldwide when diagnosis is made promptly and appropriate care is provided.

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 successfully develop or ultimately commercialize Melphalan 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 and Executive Director

Hong Kong, July 30, 2025

As at the date of this announcement, the Board 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.