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)

# CONTINUING CONNECTED TRANSACTIONS ANNOUNCEMENT PROCUREMENT OF CRO SERVICES FOR NVK002

On April 8, 2022, the Board approved the continuing connected transactions set out in this announcement and the respective annual caps for the nine months ending December 31, 2022 and the two years ending December 31, 2023 and 2024.

As the highest applicable percentage ratio for each of the proposed annual caps for the nine months ending December 31, 2022 and the two years ending December 31, 2023 and 2024 in connection with the continuing connected transactions contemplated under the CRO Service Agreements exceeds 0.1% but is less than 5%, the transactions contemplated under the CRO Service Agreements are subject to the reporting and announcement requirements but are exempt from the circular (including the appointment of an independent financial adviser) and independent Shareholders' approval requirements under Chapter 14A of the Listing Rules.

#### INTRODUCTION

In September 2021, the Group received approval from the CDE to initiate two concurrent Phase III clinical trials for NVK002, including a two-year Phase III clinical trial (the "China CHAMP") and a one-year Phase III bridging trial (the "Mini-CHAMP") in China. The latter will be combined with global data from the Company's business partner, Vyluma Inc.'s Phase III clinical trial in the U.S. and Europe. The main objective of the China CHAMP and the Mini-CHAMP is to evaluate the efficacy and safety of NVK002 in myopia progression control of children and adolescents from 3 to 17 years old.

In order to facilitate the process of the China CHAMP and the Mini-CHAMP, on April 8, 2022, Zhaoke Guangzhou entered into the CRO Service Agreements with Lee's Pharm Hefei, pursuant to which Zhaoke Guangzhou agreed to engage Lee's Pharm Hefei as a CRO service provider to provide relevant CRO services for developing NVK002 for myopia.

On April 8, 2022, the Board approved the continuing connected transactions set out in this announcement and the respective annual caps for the nine months ending December 31, 2022 and the two years ending December 31, 2023 and 2024.

# THE CRO SERVICE AGREEMENTS

Details of the CRO Service Agreements are as follows:

Date of Agreements: April 8, 2022

Parties: (i) Zhaoke Guangzhou

(ii) Lee's Pharm Hefei (as CRO service provider)

Term of Agreements: Each of the CRO Service Agreements has a term commencing

from April 8, 2022 to December 31, 2024.

Principal Terms: Pursuant to the CRO Service Agreements, Zhaoke Guangzhou

agreed to engage Lee's Pharm Hefei as a CRO service provider to provide relevant CRO services to assist Zhaoke Guangzhou

in developing NVK002 for myopia.

Payment Schedule: Payments will be made upon achievement of corresponding

milestones of the clinical trials under the CRO Service

Agreements.

Termination: Zhaoke Guangzhou is entitled to terminate the CRO Service

Agreements if the CRO services provided by Lee's Pharm Hefei are not in good quality or if Lee's Pharm Hefei materially breaches the terms of the agreements and fails to cure such

breach within a prescribed period of time.

Pricing Policy:

The service fees payable by Zhaoke Guangzhou to Lee's Pharm Hefei under the CRO Service Agreements were determined taking into account the following factors: (i) the cost and expenses to be incurred in providing such services, which are calculated based on the size and scale of each clinical trial project, including but not limited to the number of clinical centers to be engaged with and the number of patients to be recruited; (ii) the types and nature of the services, in particular, the expected complexity of the CRO services and duration of the clinical trial projects involved; (iii) the market rates for providing CRO services of similar types and nature; and (iv) the expected commitment of resources required for providing the relevant CRO services.

#### **HISTORICAL AMOUNTS**

As the Company had not engaged Lee's Pharm Hefei or any other connected person to provide CRO services for developing NVK002 in the past, no historical transaction amount is available for reference given the nature of services required for different clinical trials is materially distinct and separate from each other.

# ANNUAL CAPS AND THE BASIS

The following table sets forth the proposed annual caps for the transaction amounts under the CRO Service Agreements:

Proposed annual cap for the		
nine months		
ending	Proposed annual cap	
December 31,	for the year ending December 31,	
2022	2023	2024
	(RMB in millions)	
18.7	18.1	18.1

The proposed annual caps for each of the nine months ending December 31, 2022 and the two years ending December 31, 2023 and 2024 have been estimated in accordance with the pricing policy as stated above and primarily based on (i) the respective schedules of the research and development process for NVK002 in China-CHAMP and Mini-CHAMP; and (ii) the contemplated CRO work assigned to Lee's Pharm Hefei for conducting the specific trials to develop NVK002.

#### REASONS FOR AND BENEFITS OF THE TRANSACTIONS

As the research and development of pharmaceutical products requires significant resources, especially when a drug under development enters the clinical trial stage, it is a common practice in the pharmaceutical industry for the drug developer to engage CRO service providers to provide CRO services, including but not limited to contacting clinical centers, recruiting patients and summarizing and compiling clinical data. Following such industry practice and after going through the Group's procurement procedure, the Group has entered into several CRO service agreements with competent CRO service providers, including Lee's Pharm Hefei and other independent third parties. Based on our independent assessment and commercial judgement, and considering the overall commercial terms, the research and development capabilities and dedication proposed by Lee's Pharm Hefei and its relevant industry knowledge and experience, the Company believes engaging Lee's Pharm Hefei as our CRO service provider to provide the service contemplated under the CRO Service Agreements is commercially beneficial to the business of the Group. In addition, the Company is currently an associate of Lee's Pharm and therefore Lee's Pharm Heifei is very familiar with the Group's needs and requirements.

Dr. Li Xiaoyi, the chairman of the Board, executive Director and chief executive officer of the Company and Ms. Leelalertsuphakun Wanee, the non-executive Director of the Company, currently hold directorships in Lee's Pharm and thus have material interests in the CRO Service Agreements and the transactions contemplated thereunder. Dr. Li Xiaoyi and Ms. Leelalertsuphakun Wanee have therefore abstained from voting on the resolution of the Board in relation to the CRO Service Agreements. Save for Dr. Li Xiaoyi and Ms. Leelalertsuphakun Wanee, none of the other Directors have any material interest in the CRO Service Agreements and the transactions contemplated thereunder which require any of them to abstain from voting on the Board resolution in relation to the CRO Service Agreements and the transactions contemplated thereunder.

The Directors (including the independent non-executive Directors) are of the view that, as far as the Shareholders are concerned, the CRO Service Agreements are entered into in the ordinary course of business of the Company and on normal commercial terms, which are fair and reasonable and in the interest of the Company and the Shareholders as a whole.

# CORPORATE GOVERNANCE MEASURES

During the ordinary and usual course of business of the Group, the procurement activities are governed by the Group's procurement policy. When procurement of raw materials or services or procurement from new suppliers is necessary, the Company would strictly follow the Group's internal procurement policy to select suppliers, raw materials or services. When selecting CRO service providers, the Group's procurement team normally requests the potential supplier to provide, among others, its industrial background and credentials, an initial service plan designed by the CRO service provider and the quotations with breakdown of detailed components of the CRO services and procedures involved. Furthermore, the

Group's procurement department routinely monitors market price for procurement of raw materials and relevant services necessary for the Group's business, for benchmarking and cost control purposes.

The commercial negotiations with potential suppliers are usually led by the chief operating officer and the head of the procurement department of the Group, who will independently evaluate the terms taking into account all relevant factors as the Group considers necessary. A decision on whether to engage such supplier will be made purely based on commercial considerations and only if the Company considers it is in the best interest of the Company and the Shareholders to enter into such procurement arrangement.

# LISTING RULES IMPLICATION

As of the date of this announcement, Zhaoke Guangzhou was indirectly wholly owned by the Company and Lee's Pharm, through Lee's Pharm International and Lee's Healthcare Industry Fund L.P., was interested in approximately 25.9% of the total issued share capital of the Company, being a Substantial Shareholder of the Company. Lee's Pharm Hefei is a subsidiary of Lee's Pharm. Thus, Lee's Pharm Hefei is a connected person of the Company under the Listing Rules and the transactions under the CRO Service Agreements constitute continuing connected transactions of the Company under Chapter 14A of the Listing Rules.

The transactions contemplated under the CRO Service Agreements and the Master CRO Service Agreement are not aggregated under Rule 14A.81 of the Listing Rules, given that (i) the Master CRO Service Agreement and the transactions contemplated thereunder have been terminated; (ii) the drug candidates to be developed and their corresponding clinical trials under the CRO Service Agreements and the Master CRO Service Agreement respectively are totally different; and (iii) the details of CRO services provided by Lee's Pharm Hefei under the CRO Service Agreements and the Master CRO Service Agreement respectively are distinct from each other considering the differences in the subject drug candidates and the respective clinical trials.

As the highest applicable percentage ratio for each of the proposed annual caps for the nine months ending December 31, 2022 and the two years ending December 31, 2023 and 2024 in connection with the continuing connected transactions contemplated under the CRO Service Agreements exceeds 0.1% but is less than 5%, the transactions contemplated under the CRO Service Agreements are subject to the reporting and announcement requirements but are exempt from the circular (including the appointment of an independent financial adviser) and independent Shareholders' approval requirements under Chapter 14A of the Listing Rules.

# **GENERAL**

The Company is an ophthalmic pharmaceutical company dedicated to the research, development, manufacturing and commercialization of therapies that address significant unmet medical needs in China and is strategically focused on treatments that cover a wide range of ophthalmic diseases.

Zhaoke Guangzhou is a limited liability company established under the laws of the PRC on June 16, 2016, primarily engaging in research and development, and commercialization of ophthalmic drugs, and is the principal operating subsidiary of the Group. As of the date of this announcement, Zhaoke Guangzhou is wholly owned by the Company.

Lee's Pharm Heifei is principally engaged in providing CRO services and is currently operating a manufacturing plant located in Hefei, Anhui Province of the PRC, comprising four GMP-compliant workshops for the production of topical gel, lyophilised powder for injection and small volume parenteral solutions.

# **DEFINITIONS**

"Board" the board of Directors

"CDE" the Center for Drug Evaluation of National Medical Products Administration (國家藥品監督管理局藥品審評中心)

"Company" Zhaoke Ophthalmology Limited (兆科眼科有限公司) (previously known as China Ophthalmology Focus Limited), a company incorporated in the British Virgin Islands on January 20, 2017 with limited liability and continued in the Cayman Islands on April 29, 2020 as an exempted company with limited liability, the Shares of which are listed on the Main Board of the Stock Exchange (Stock Code: 6622)

"connected person(s)" has the meaning ascribed to it under the Listing Rules

"connected transaction(s)" has the meaning ascribed thereto under the Listing Rules

"CRO" contract research organization, a company that provides

support to pharmaceutical companies by providing a range of

professional research services on a contract basis

"CRO Service Agreements" the CRO service agreements entered into by and between

Zhaoke Guangzhou and Lee's Pharm Hefei on April 8, 2022 for

developing NVK002

"Director(s)" the director(s) of the Company

"GMP" good manufacturing practice

"Group" the Company and its subsidiaries

"Hong Kong" the Hong Kong Special Administrative Region of the PRC "Lee's Pharm" Lee's Pharmaceutical Holdings Limited (李氏大藥廠控股有 限公司), an exempted company incorporated in the Cayman Islands with limited liability whose shares are listed on the Main Board of the Stock Exchange (stock code: 950) "Lee's Pharm Hefei" Zhaoke Pharmaceutical (Hefei) Company Limited (兆科藥業 (合肥) 有限公司), a limited liability company established in the PRC on February 7, 1994 and a subsidiary of Lee's Pharm "Lee's Pharm International" Lee's Pharmaceutical International Limited, a limited liability company incorporated in the British Virgin Islands on August 1, 2001 and a subsidiary of Lee's Pharm "Listing Rules" The Rules Governing the Listing of Securities on the Stock Exchange, as amended from time to time "Master CRO Service the master CRO service agreement entered into between Zhaoke Agreement" Guangzhou and Lee's Pharm Hefei on April 1, 2021, pursuant to which the Group agreed to engage Lee's Pharm Hefei as a CRO service provider to provide relevant CRO services for developing CsA ophthalmic gel, ZKY001 and levobetaxolol HCl of the Group. The Master CRO Service Agreement has been terminated in the first quarter of 2022 "percentage ratio(s)" has the meaning ascribed to it under the Listing Rules "PRC" or "China" the People's Republic of China. For the purposes of this announcement only and except where the context requires otherwise, excludes Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan "Share(s)" ordinary shares in the share capital of the Company of

US\$0.0000025 each

"Shareholder(s)" the holder(s) of the Shares

"Stock Exchange" The Stock Exchange of Hong Kong Limited

"Substantial Shareholder(s)" has the meaning ascribed to it under the Listing Rules

"U.S." the United States of America, its territories, its possessions and

all areas subject to its jurisdiction

"Zhaoke Guangzhou" Zhaoke (Guangzhou) Ophthalmology Pharmaceutical Co., Ltd.

(兆科 (廣州) 眼科藥物有限公司), a limited liability company established in the PRC on June 16, 2016 and an indirect wholly

owned subsidiary of the Company

"%" per cent

By order of the Board

Zhaoke Ophthalmology Limited

Dr. Li Xiaoyi

Chairman

Hong Kong, April 8, 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 Dr. Tam Lai Fan Gloria as independent non-executive Directors.