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**TYK Medicines, Inc**

**浙江同源康醫藥股份有限公司**

*(A joint stock company incorporated in the People's Republic of China with limited liability)  
(Stock Code: 2410)*

## **VOLUNTARY ANNOUNCEMENT**

### **ACCEPTANCE OF NEW DRUG APPLICATION FOR ASANDEUTERTINIB (TY-9591) BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION**

This announcement is made by TYK Medicines, Inc (浙江同源康醫藥股份有限公司) (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business developments of the Group.

The board of directors (the “**Board**”) of the Company is pleased to announce that the New Drug Application (the “**NDA**”) for the Company’s investigational Class 1 new drug, Asandutertinib (TY-9591), has been accepted by the Center for Drug Evaluation (the “**CDE**”) of the National Medical Products Administration (the “**NMPA**”). Relevant information is now announced as follows:

#### **DRUG OVERVIEW**

Drug name	Asandutertinib (TY-9591)
Specification	40mg
Acceptance number	CXHS2600026
Application item	Registration of Domestic Drug Marketing Authorization
Applicant	TYK Medicines, Inc
Review conclusion	It is decided to be accepted upon review according to the requirements of Article 32 of the Administrative License Law of the People's Republic of China (《中華人民共和國行政許可法》).

## ABOUT ASANDEUTERTINIB (TY-9591)

Asandeutertinib (TY-9591) is a deuterated analog of osimertinib, exhibiting high bioavailability and enhanced brain penetration. This NDA registration application is for the indication of first-line treatment of adult patients with locally advanced or metastatic NSCLC harboring EGFR exon 19 deletion (19DEL) or exon 21 (L858R) substitution mutation, and with CNS metastases. The data of Phase I (TYKM1601101) and Phase II (TYKM1601201) clinical studies have preliminarily demonstrated exceptional intracranial and systemic response rates in patients with brain metastases from NSCLC, delivering significant clinical benefit and addressing unmet clinical needs. Data from the pivotal Phase II clinical study (TYKM1601202) further confirmed its superior efficacy, demonstrating higher intracranial response rates and clinical benefit compared to osimertinib. Asandeutertinib (TY-9591) has significant clinical value for treating patients with brain metastases from lung cancer with EGFR mutations.

As a deuterated compound of osimertinib, Asandeutertinib (TY-9591) demonstrates superior clinical value and advantages in terms of chemical structure, pharmacological effects, clinical efficacy and safety, as well as resistance mechanism analysis, and has a significant effect on improving disease prognosis.

## RISK WARNING

The acceptance of the application is merely an administrative step in the review process and does not constitute marketing authorization. The product is subject to further review and evaluation by the NMPA, and there is no guarantee that the application will be approved.

As pharmaceutical products are characterized by high technology, high risks and high added value, and require a long development cycle with many stages from preliminary R&D, clinical trial application and approval to launch, they are vulnerable to multiple uncertainties, and there is uncertainty as to whether or not this New Drug Application will be approved.

**Warning under Rule 18A.05 of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited:** There is no assurance that the relevant product will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By Order of the Board

**TYK Medicines, Inc**

(浙江同源康醫藥股份有限公司)

**Dr. WU Yusheng**

*Chairman, Executive Director and Chief Executive Officer*

Hong Kong, February 6, 2026

*As at the date of this announcement, the Board comprises Dr. WU Yusheng as executive Director, Dr. LI Jun, Dr. GU Eric Hong, Dr. JIANG Mingyu, Mr. HE Chao and Dr. ZHU Xiangyang as non-executive Directors, and Dr. LENG Yuting, Dr. XU Wenqing, Dr. SHEN Xiuhua and Mr. JIANG Xiaolin as independent non-executive Directors.*