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

INCLUSION OF ASANDEUTERTINIB (TY-9591) IN THE LIST OF PRODUCTS FOR PRIORITY REVIEW BY THE CENTER FOR DRUG EVALUATION OF 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 Company's investigational Class 1 new drug, Asandeutertinib (TY-9591), has been included in the List of Products for Priority Review (優先審評品種名單) 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	Asandeutertinib (TY-9591)
Dosage form and specification	Tablet, 40mg
Registration category	Chemical drug, class 1
Applicant	TYK Medicines, Inc
Proposed indication	First-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring epidermal growth factor receptor (EGFR) exon 19 deletion (19DEL) or exon 21 (L858R) substitution mutation, and with central nervous system (CNS) metastases.

Reasons for priority review	Upon review, the application is in compliance with relevant requirements under the Administration Measures for Drug Registration (《藥品註冊管理辦法》) and the Announcement of NMPA on Promulgating Three Documents Including the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (Trial) (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》) (No. 82 2020), and it is agreed to be granted priority review according to the prioritized examination scope "(5) Drugs that are eligible for conditional approval".

DISEASE BACKGROUND AND CLINICAL VALUE OF THE DRUG

Asandeutertinib (TY-9591) is intended for the 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.

According to the 2025 latest data from the World Health Organization (WHO), the number of new lung cancer cases exceeds 2.5 million globally each year, with 1.8 million deaths. In China, the number of new lung cancer cases will exceed 1 million each year, with approximately 75% of patients diagnosed at a middle or advanced stage, resulting in a five-year survival rate below 20%. The incidence of brain metastases in patients with advanced NSCLC can reach as high as 57%. For advanced NSCLC with EGFR mutations, the incidence of brain metastases exceeds 60%, with the cumulative incidence increasing annually as survival periods extend. The natural average survival period is only 1 to 2 months, and the poor prognosis severely threatens the lives and quality of life of patients, urgently requiring safe and effective clinical drugs.

Currently, no third-generation EGFR-TKIs have been approved for marketing globally for the indication of brain metastases from NSCLC. The reported efficacy data for marketed third-generation EGFR-TKIs such as osimertinib, almonertinib, and furmonertinib are all derived from retrospective subgroup analyses, and the sample size is limited (13 to 28 cases), lacking sufficient statistical power to draw confirmatory conclusions. Prospective, randomized, controlled confirmatory clinical studies targeting the population with brain metastases are still required to change clinical practice or support the addition of brain metastases from NSCLC as an indication to drug labeling.

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 inclusion of Asandeutertinib (TY-9591) in the List of Products for Priority Review (優先審評品種名單) by the CDE is an initial recognition of the clinical value of Asandeutertinib (TY-9591) and marks a significant acceleration in the review process, potentially enabling earlier market launch to benefit Chinese patients. However, the final review and approval remains subject to a comprehensive technical evaluation and carries inherent uncertainties. Investors are advised to consider the following risks:

UNCERTAINTY OF REVIEW AND APPROVAL

The subsequent review and approval of drugs still needs to pass the technical evaluation by CDE and the administrative approval by the NMPA, and there are uncertainties as to whether or not the drugs will be finally approved for marketing and the timing of such approval.

RESEARCH AND DEVELOPMENT ("R&D") AND INDUSTRY RISK

As pharmaceutical products are characterized by high technology, high risks and high added value, and require a long R&D cycle and many stages, which makes them vulnerable to multiple uncertainties such as technology, approval and market.

The Company will continue to promote the follow-up work of this product and perform its information disclosure obligations in a timely manner in strict accordance with relevant laws and regulations.

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, January 29, 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.