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

LATEST PIVOTAL STUDY RESULTS OF ASANDEUTERTINIB AS FIRST-LINE TREATMENT FOR ADVANCED NON-SMALL CELL LUNG CANCER WITH BRAIN METASTASES PRESENTED AS LBA AT 2026 ASCO ANNUAL MEETING

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 interim analysis results from the pivotal Phase II ESAONA study of the Company's independently developed asandeutertinib (TY-9591) vs. osimertinib as first-line treatment for epidermal growth factor receptor (EGFR)-mutant non-small cell lung cancer (NSCLC) patients with brain metastases have been presented orally as a late-breaking abstract ("**LBA**") at the 2026 Annual Meeting of the American Society of Clinical Oncology ("**ASCO**").

STUDY BACKGROUND

EGFR tyrosine kinase inhibitors (TKIs) have delivered significant survival benefits to patients with EGFR-sensitive mutant NSCLC, but their efficacy remains limited for those with brain metastases that severely threaten life, health, and quality of life. Asandeutertinib is a novel, third-generation EGFR-TKI that has demonstrated favorable intracranial efficacy and safety in two early-phase clinical studies (NCT04204473, NCT05146219).

STUDY METHODS

The ESAONA study is an open-label, multicentre, randomised controlled pivotal Phase II clinical study, designed to evaluate the efficacy and safety of asandeutertinib vs. osimertinib as first-line therapy in NSCLC patients with classic EGFR mutations and brain metastases. Eligible patients were randomised at a 1:1 ratio to the asandeutertinib group (160mg QD) or the osimertinib group (80mg QD), stratified by EGFR mutation subtype (19Del or L858R) and number of intracranial lesions (>3 or ≤3).

The primary endpoints of the study include intracranial objective response rate (iORR) and intracranial progression-free survival (iPFS) assessed by Blinded Independent Central Review (BICR) per RECIST v1.1. Secondary endpoints include iORR and iPFS assessed by investigators (INV) per RECIST v1.1 and RANO-BM, ORR and PFS assessed by BICR and INV, intracranial duration of response (iDoR), overall survival (OS), and safety.

STUDY RESULTS

As of the data cutoff date of December 15, 2025, the median follow-up duration of the study was 19.12 months. A total of 224 patients were enrolled in the two groups (111 in the asandeutertinib group and 113 in the osimertinib group), with balanced and comparable baseline characteristics between the two groups.

Intracranial Efficacy

Confirmed BICR-iORR was significantly superior in the asandeutertinib group compared to the osimertinib group (95.5% vs. 79.6%), with a between-group difference in iORR adjusting for stratification factors of 15.62% (95% CI: 6.66%, 24.34%; P=0.0004). Significant benefits in the asandeutertinib group were observed across all subgroups defined by prespecified stratification factors.

BICR-iPFS data were not yet mature. The median iPFS was Not Reached (95% CI: 22.4-NA) in the asandeutertinib group vs. 17.51 months (15.18-NA) in the osimertinib group, HR=0.46 (95% CI: 0.28-0.76; P=0.0020). The 18-month and 24-month iPFS rates were 75.24% (95% CI: 63.40%-83.73%) vs. 48.12% (95% CI: 36.11%-59.14%), and 61.56% (95% CI: 39.95%-77.37%) vs. 38.28% (95% CI: 24.82%-51.59%), respectively. The iPFS benefit in the asandeutertinib group was consistent across all subgroups.

iDoR data were not yet mature. The median BICR-iDoR was Not Reached (95% CI: 20.83-NA) in the asandeutertinib group vs. 16.26 months (95% CI: 13.83-NA) in the osimertinib group, HR=0.50 (95% CI: 0.28-0.88; P=0.0148).

Significant benefits in the asandeutertinib group were also observed for investigator-assessed iORR and iPFS per RECIST v1.1. The confirmed iORR was 92.8% vs. 77.9% (P=0.0019); the median iPFS was Not Reached (95% CI: 21.45-NA) vs. 17.51 months (95% CI: 15.38-21.36), HR=0.56 (95% CI: 0.36-0.89; P=0.0122). The 18-month and 24-month iPFS rates were 69.62% (95% CI: 57.85%-78.70%) vs. 48.54% (95% CI: 36.75%-59.35%) and 50.77% (95% CI: 31.59%-67.11%) vs. 32.28% (95% CI: 19.71%-45.50%), respectively.

The investigator-assessed iORR and iPFS results per RANO-BM were consistent with those assessed per RECIST v1.1. The confirmed iORR was 91.9% vs. 77.9% (P=0.0039); median iPFS was 22.64 months (95% CI: 21.45-NA) vs. 17.51 months (95% CI: 15.21-21.36), HR=0.60 (95% CI: 0.39-0.94; P=0.0232).

Systemic Efficacy

Confirmed BICR-ORR was 89.2% in the asandeutertinib group vs. 77.9% in the osimertinib group (P=0.0301).

PFS data were not yet mature. The median PFS was Not Reached (95% CI: 17.22-NA) in the asandeutertinib group vs. 17.22 months (15.18-19.55) in the osimertinib group, HR=0.64 (95% CI: 0.41-1.00; P=0.0473).

OS data were not yet mature and follow-up is ongoing.

Safety

All 111 patients (100%) in the asandeutertinib group and 112 patients (99.1%) in the osimertinib group experienced treatment-emergent adverse events (TEAEs), of whom 55 patients (49.5%) and 24 patients (21.2%) had Grade 3 or higher TEAEs respectively. Most Grade 3 and above adverse events were relieved or recovered after symptomatic treatment and dose reduction. Permanent discontinuation due to treatment-related adverse events (TRAEs) occurred in four patients in each group.

CONCLUSION AND OUTLOOK

The superior intracranial efficacy and manageable safety of asandeutertinib support its potential as a new first-line treatment option for EGFR-sensitive mutant NSCLC patients with brain metastases. At present, the New Drug Application (NDA) for asandeutertinib has been accepted by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) and included in the priority review and approval procedure.

iPFS/PFS and OS data from the ESAONA study remain immature, and follow-up is ongoing. In addition, several other studies of asandeutertinib as monotherapy or in combination are being conducted in China.

ABOUT ASANDEUTERTINIB

Asandeutertinib is a highly potent, ATP-competitive, irreversible, oral high-selectivity next-generation EGFR-TKI independently developed by TYK Medicines, Inc. As a deuterated product of the marketed agent osimertinib, it exhibits a distinct pharmacokinetic profile, markedly reduces the production of the toxic metabolite AZD5104 (TY9591-D1), and offers significant clinical advantages, particularly remarkable efficacy in NSCLC patients with brain metastases and EGFR L858R sensitizing mutations. TYK Medicines has initiated multiple clinical trials of asandeutertinib as monotherapy and combination therapy for advanced NSCLC patients in China.

ABOUT THE COMPANY

TYK Medicines, Inc is an international innovative biopharmaceutical company focusing on the research and development of next-generation kinase inhibitors to address unmet clinical needs in cancer treatment. Since its establishment in 2017, TYK Medicines has developed over a dozen innovative drug candidates covering multiple stages from PCC to Phase III clinical trials. The Company is committed to providing patients with more effective and safer anti-tumour drugs.

Warning Statement 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 Company will ultimately be able to successfully develop and commercialize the relevant products. 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, May 31, 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.