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 EGFR-TARGETED INNOVATIVE DRUG ASANDEUTERTINIB DEMONSTRATES BREAKTHROUGH EFFICACY IN NSCLC PATIENTS WITH BRAIN METASTASES — INTERIM RESULTS FROM THE ESAONA PIVOTAL STUDY ANNOUNCED AT WCLC 2025

This announcement is made by TYK Medicines, Inc (浙江同源康醫藥股份有限公司) (the "**Company**" or "**TYK Medicines**", 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 (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the results from the pivotal Phase II registrational clinical trial (NCT05948813) of its independently developed innovative drug Asandeutertinib (TY-9591) for the treatment of EGFR-mutant non-small cell lung cancer (NSCLC) have been accepted as a mini oral presentation (MA08.06) at the 2025 World Conference on Lung Cancer (WCLC), organized by the International Association for the Study of Lung Cancer (IASLC). The data will be presented by the principal investigator, Professor Yuankai Shi from the Cancer Hospital, Chinese Academy of Medical Sciences.

Study Background

Asandeutertinib (TY-9591) is a highly selective small-molecule inhibitor developed by TYK Medicines, targeting classical EGFR mutations, designed to address the unmet clinical need for more effective treatments for brain metastases in NSCLC under current standard of care.

The ESAONA pivotal trial, selected for mini oral presentation, is an open-label, multicenter, randomized, phase II study focused on patients with EGFR mutations (L858R or 19Del) and brain metastases. The aim is to compare the first-line efficacy and safety of asandeutertinib (160 mg once daily) versus osimertinib (80 mg once daily) in untreated EGFR-mutant NSCLC patients with brain metastases. Primary endpoints include: intracranial objective response rate (iORR) and intracranial progression-free survival (iPFS). Secondary endpoints include: objective response rate (ORR), progression-free survival (PFS), overall survival (OS), disease control rate (DCR), depth of response (DepOR), and safety, et.al. Two interim analyses are planned: the first when 220 patients with evaluable intracranial lesions are reached, and the second when 238 iPFS events occur. Final analysis will be conducted upon reaching all planned iPFS events. If primary endpoints were met, data from the first interim analysis would be submitted to the National Medical Products Administration (NMPA) to apply for conditional approval. Final data will support a full approval application.

KEY RESULTS

Efficacy

As of February 28, 2025, 257 EGFR-mutant NSCLC patients with brain metastases had been enrolled. Based on interim analysis of 224 patients, BICR-assessed iORR of asandeutertinib was 91.9% (95% CI: 85.2-96.2%) vs. 76.1% (95% CI: 67.2-83.6%, P = 0.001) of osimertinib; investigator-assessed iORR of asandeutertinib was 91.0% (95% CI: 84.1-95.6%) vs. 75.2% (95% CI: 66.2-82.9%, P = 0.002) of osimertinib. Overall ORR favorable trended asandeutertinib with 84.7% comparing osimertinib with 75.2%. iPFS, PFS, OS, and other efficacy data were not yet mature.

Safety

The incidence of ≥Grade 3 treatment-related adverse events (TRAEs) was 31.5% in the asandeutertinib group vs. 15.0% in the osimertinib group. The most common ≥Grade 3 TRAEs with asandeutertinib included elevated creatine phosphokinase, QTcf interval prolongation, neutropenia, and leukopenia. Interstitial lung disease (ILD) occurred in 9.9% of patients, and QTcf prolongation occurred in 4.5% of patients. All AEs were manageable and could be monitorable.

Significance

Led by Professor Yuankai Shi and conducted across 51 centers nationwide, this study shows that asandeutertinib, a developed next-generation EGFR-TKI, showed excellent therapeutic effects in controlling brain metastatic lesions and alleviating the condition. It has the potential to become a new and more effective first-line treatment option for EGFR-mutant NSCLC patients with brain metastases. The research team will continue follow-up to obtain mature iPFS, PFS, and OS data, aiming to bring this innovative therapy to patients as soon as possible.

About the World Conference on Lung Cancer (WCLC)

The WCLC is the largest global academic conference in the field of lung cancer, organized annually by the IASLC, attracting experts, researchers, and industry representatives from around the world. The conference focuses on basic research, clinical advancements, and innovative therapies in lung cancer, serving as a key platform for advancing diagnostic and treatment technologies. Oral presentations are reserved for studies with high scientific innovation, clinical relevance, and breakthrough data. The mini oral format typically highlights key early-phase (Phase I/II) trial results with potential to change clinical practice. The invitation for asandeutertinib's (TY-9591) pivotal Phase II results reflects international recognition of its efficacy and safety, underscoring its significant clinical translation potential.

About TYK Medicines, Inc.

TYK Medicines, Inc. is a biopharmaceutical company focused on the development of innovative oncology therapies. Through independent research and development and global collaboration, the company is committed to delivering breakthrough treatment solutions for patients. TYK Medicines currently has multiple innovative programs in clinical and preclinical stages, building a robust and diverse product pipeline.

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 be able to develop, market and/or commercialize TY-9591 successfully. 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, August 14, 2025

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