**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
# INVESTIGATOR DATA SHOW PIVOTAL PHASE II CLINICAL TRIAL OF TY-9591 VERSUS OSIMERTINIB AS A FIRST-LINE TREATMENT FOR BRAIN METASTASES FROM LUNG CANCER WITH EGFR MUTATIONS MET EXPECTATIONS WITH STATISTICAL AND CLINICAL SIGNIFICANCE

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 of the Company (the "**Board**") is pleased to announce that the pivotal Phase II clinical trial of the Company's internally-developed TY-9591 (trade name: Kardorisso®) versus osimertinib (trade name: Tagrisso®) as a first-line treatment for brain metastases from lung cancer with EGFR mutations shows statistical and clinical significance based on investigator data. The intracranial objective response rate (iORR) as the primary study endpoint achieved expected outcome and TY-9591 demonstrated notably improved statistical and clinical significance over osimertinib. TY-9591 versus osimertinib showed obvious statistical differences, either in the whole group or among different subgroups (including genes types, number of intracranial lesions and ECOG scores, etc.).

The trial results show that:

- The iORR, as the primary study endpoint, met expectations and TY-9591 demonstrated notably improved statistical and clinical significance over osimertinib.

- TY-9591 is the first and only drug in the world demonstrating significant superiority over osimertinib for indications of brain metastases from lung cancer with EGFR mutations in the clinical study of monotherapy head-to-head comparison with osimertinib.

- In patients with brain metastases from lung cancer with EGFR mutations (exon 19 deletion and exon 21 L858R mutation), the TY-9591 was significantly superior to the osimertinib in all subgroups by iORR.

- The TY-9591 showed strong positive results in all subgroups (including the number of intracranial lesions and ECOG score, etc.).

- Among 224 enrolled subjects in the trial, 53.1% had a deletion of exon 19 and 46.9% had a mutation in exon 21 L858R, in line with the distribution of mutation levels in real-world patients.

- The TY-9591 demonstrated an overall favorable safety profile, with no new safety signals observed.

- Detailed data from this clinical study will be presented at international or domestic clinical conferences in the near future.

The Company plans to submit an NDA (New Drug Application) to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in the near future.

**ABOUT TY-9591**

TY-9591 is a tyrosine kinase inhibitor (TKI) developed for, and demonstrates significant efficacy in, patients with brain metastases from lung cancer with EGFR mutations. TY-9591 is able to effectively cross the blood-brain barrier to irreversibly bind EGFR mutants (including exon 19 deletion and exon 21 L858R mutation: exon 19 deletion/T790M mutation and L858R/T790M mutation), and ultimately inhibit the proliferation and metastasis of cancer cells.

There were aggregately 127 patients enrolled in the Phase I/II clinical study of the Company and the overall safety profile was favorable. Among the 29 patients with measurable brain metastases from lung cancer with EGFR mutations, 25 achieved intracranial PR (Partial Response) and 4 achieved intracranial CR (Complete Response), with overall iORR of 100%. Based on the encouraging Phase I/II clinical data, the CDE granted approval for the Company to conduct the pivotal Phase II clinical trial of TY-9591 monotherapy as first-line treatment of brain metastases from lung cancer with EGFR mutations.

**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, March 9, 2025

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