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 CLINICAL POSITIVE DATA FOR CDK INHIBITORS ANNOUNCED AT ESMO CONGRESS 2025

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 (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the early-phase clinical study results for three of our key cyclin-dependent kinase ("**CDK**") inhibitor (CDKi) candidates, TYK-00540 (CDK2/4i), TY-2699a (CDK7i) and TY-302 (CDK4/6i), were presented as posters at the European Society for Medical Oncology ("**ESMO**") Congress.

ESMO Congress 2025 was held from October 17 to 21, 2025 (local time) in Berlin, Germany. As one of the most influential academic events in the field of oncology worldwide, the ESMO Congress attracted many leading professionals from the academic community, providing a platform for discussing clinical challenges and sharing leading-edge developments.

CLINICAL STUDY OF TYK-00540

Study Title

Safety and Preliminary Efficacy of TYK-00540 (A Novel CDK2/4 inhibitor) in Patients with Advanced Solid Tumors: Results of Phase I Dose-escalation Study (FPN 505P).

Principal Investigator

Professor Zhang Jian from Fudan University Shanghai Cancer Center.

Background

CDK4/6i has become the cornerstone of first-line therapy for HR+/HER2- advanced breast cancer (BC), but drug resistance remains inevitable. Preclinical studies showed that CDK2i could overcome CDK4/6i resistance, and therefore dual inhibition of CDK2/4 may be the effective solutions to improve patients' clinical benefits. TYK-00540 is a novel CDK2/4i developed for the treatment of CDK4/6i-resistant HR+/HER2- BC. This is a first-in-human, dose-escalation Phase I study (NCT06950086), aiming to investigate the safety, tolerability, pharmacokinetic (PK) characters and preliminary efficacy of TYK-00540 in patients suffering advanced solid tumors.

Methodology

This Phase I study comprises three stages, including monotherapy dose-escalation studies (Part 1), combination dose selection (combination with fulvestrant (氟維司群), Part 2) and dose expansion (Part 3). Part 1 enrolled patients with HR+/HER2- mBC, triple-negative breast cancer (TNBC), ovarian cancer (OC) and non-small cell lung cancer (NSCLC), giving them TYK-00540 monotherapy. Part 2 enrolled patients with HR+/HER2- mBC and gave them TYK-00540 in combination with fulvestrant. Part 3 enrolled patients with HR+/HER2- mBC and OC, divided into four groups based on cancer type, previous endocrine therapy and CDK4/6i use, to receive TYK-00540 monotherapy or TYK-00540 in combination with fulvestrant, respectively.

Key Results

Patient Baseline Characteristics

As of July 15, 2025, a total of 24 patients were enrolled in the monotherapy dose-escalation stage, including 16 patients who had previously received CDK4/6i treatment. These 24 patients include 15 patients with HR+/HER2- BC who had previously received both endocrine therapy and at least one type of CDK4/6i treatment.

Safety

Among the 24 patients, 11 patients (45.8%) experienced Grade 3 or higher treatment-related adverse events (TRAEs) and 2 patients (8.3%) experienced Grade 3 or higher treatment-related serious adverse events (TRSAEs). Common adverse drug reactions mainly included hematologic toxicities, as well as nausea and vomiting, which could be effectively alleviated after treatment intervention. No cases of permanent drug discontinuation or death due to TRAEs occurred.

Efficacy

Among the 13 patients with HR+/HER2- BC available for evaluation, 2 patients achieved confirmed partial response (PR) and 5 achieved stable disease (SD), representing an objective response rate (ORR) of 15.4% (2/13) and a disease control rate (DCR) of 53.8% (7/13).

PK Characters

TYK-00540 exposure increased with increasing dose, with a median Tmax of 1 to 4 hours and a median T1/2 of 3.98 to 5.67 hours. Slight accumulation was observed across doses.

Conclusion

The primary adverse events of TYK-00540 monotherapy are hematologic toxicities, which can be effectively alleviated after drug suspension or treatment intervention, with an overall manageable safety profile. It has demonstrated encouraging efficacy in patients with HR+/HER2- mBC who have received multiple treatments and are resistant to CDK4/6 inhibitors. Based on comprehensive safety and efficacy data, 30mg Bid has been established as the recommended dose for expansion (RDE) of TYK-00540.

A study of TYK-00540 in combination with fulvestrant (NCT06950086) is ongoing in the hope of further addressing the unmet clinical needs of such patients.

According to latest clinical trial results, among the 5 patients with platinum-resistant ovarian cancer treated with TYK-00540 monotherapy available for evaluation, the ORR was 20% (1/5) and the DCR was 60% (3/5). Among the 3 patients with HR+/HER2- BC treated with TYK-00540 in combination with fulvestrant available for evaluation, the ORR was 33.3% (1/3) and the DCR was 100% (3/3). The study is ongoing.

CLINICAL STUDY OF TY-2699A

Study Title

Phase I Dose-escalation Study of TY-2699a (A Non-covalent CDK7 Inhibitor) in Patients with Advanced Solid Tumors (FPN975P).

Principal Investigator

Academician Xu Binghe from the Cancer Hospital of the Chinese Academy of Medical Sciences.

Study Background

CDK7 plays a crucial role in regulating cell division, transcription processes and nuclear receptor activity. CDK7i has emerged as a promising novel anti-tumor strategy. TY-2699a is a selective, non-covalent, oral CDK7 inhibitor. We hereby report the preliminary results of Phase I study (NCT05866692), which is focused on safety, tolerability and pharmacokinetics (PK) under a twice-daily (Bid) dosing regimen over a 28-day treatment cycle.

Key Results

This Phase I clinical study, employing a BOIN design, enrolled 20 patients with advanced solid tumors across five dose-escalation cohorts. The results showed that continuous Bid dosing of TY-2699a enabled a relatively high dose levels with manageable safety and preliminary anti-tumor activity. 3 patients achieved SD, including one with TNBC in the 5mg cohort and two with HR+/HER2- mBC in the 20mg and 30mg cohorts respectively, all of whom are still receiving treatment in their respective cohorts. These findings support further investigation of intermittent dosing regimens and combination therapies.

CLINICAL STUDY OF TY-302 IN COMBINATION WITH TOREMIFENE

Study Title

Phase Ia/Ib Clinical Study of TY-302 (A CDK4/6 Inhibitor) in Combination with Toremifene in Patients with Advanced Solid Tumors (FPN513P).

Principal Investigators

Academician Xu Binghe/Professor Ma Fei from the Cancer Hospital of the Chinese Academy of Medical Sciences.

Study Background

TY-302 is a potent and selective oral cyclin-dependent kinase (CDK) 4/6 inhibitor developed for the treatment of advanced solid tumors, including breast cancer or prostate cancer. By targeting CDK4/6, a key cell regulator, TY-302 suppresses the phosphorylation of the retinoblastoma protein (Rb), thereby inhibiting proliferation of cancer cells. TY-302 is currently the only CDK4/6 inhibitor indicated for prostate cancer among numerous CDK drugs candidates. We hereby report the safety, PK characters and preliminary efficacy results of TY-302 in combination with toremifene in patients with advanced breast cancer in the first-in-human Phase Ia/Ib study (NCT04433494).

Key Results

Phase I clinical results showed that TY-302 (100mg QD) in combination with toremifene exhibited positive antitumor activity with manageable toxicity in patients with HR+/HER2- mBC. Grade 3 or higher treatment-emergent adverse events (TEAEs) were primarily hematologic toxicities. Among 31 patients with HR+/HER2- mBC who received TY-302 (100mg) + toremifene, the ORR was 19.4% (6/31), the DCR was 77.4% (24/31) and the median progression-free survival (mPFS) was 8.2 months. These findings support further exploration of this regimen in such patients.

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.

There is no assurance that the Company will be able to develop, market and/or commercialize TYK-00540, TY-2699a and TY-302 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, October 21, 2025

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 and Dr. SHEN Xiuhua as independent non-executive Directors.