SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)
Website: www.sinobiopharm.com
(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT
PHASE III STUDY RESULTS OF CULMERCICLIB IN COMBINATION WITH FULVESTRANT FOR TREATMENT OF HR+/HER2- ADVANCED BREAST CANCER FOLLOWING ENDOCRINE TREATMENT PRESENTED AT 2024 CSCO

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the latest results of the phase III clinical study (TQB3616-III-01) of Culmerciclib, a Category 1 innovative drug developed by the Group, in combination with Fulvestrant for the treatment of patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) advanced breast cancer following endocrine treatment was presented at the 2024 National Congress of Clinical Oncology (2024 CSCO) by oral presentation: The median progression-free survival (PFS) was 16.62 months, the objective remission rate (ORR) was 40.21%, and the overall survival (OS) showed a favourable trend.

TQB3616-III-01 is the first phase III clinical study in the world achieved positive results for oral CDK2/4/6 inhibitor in combination with endocrine treatment for the treatment of HR+/HER2- advanced breast cancer. It is a randomised, double-blind, parallel-controlled, multicentre clinical study designed to evaluate the efficacy and safety of Culmerciclib in combination with Fulvestrant (experimental group) versus placebo combined with Fulvestrant (control group) in patients with HR+/HER2- advanced breast cancer following endocrine treatment.

Dual statistically and clinically significant benefit in primary endpoint PFS[1]

The results showed that the median PFS of Culmerciclib in combination with Fulvestrant group versus placebo in combination with Fulvestrant group was 16.62 months vs. 7.46 months. As compared with the control group, the median PFS of Culmerciclib combination therapy was extended by 9.16 months, and the risk of disease progression/death was reduced by 64% (HR = 0.36, $p < 0.0001$). The median PFS, hazard ratio (HR) and absolute degree of PFS benefit for the primary study outcomes were all higher than the data available for standard treatment.

Effective tumour remission and a trend towards survival benefit[1]

Culmerciclib combination therapy significantly improved the confirmed ORR in patients compared with the control group (40.21% vs. 12.12%), and the confirmed ORR improvement was even more pronounced in the population of patients with measurable lesions (46.43% vs. 14.12%). Currently, OS data are not yet mature, but Culmerciclib combination therapy has shown a trend towards OS benefit.

Significant benefit of Culmerciclib in combination with Fulvestrant in various subgroups[1]

PFS subgroups analysis showed that in all prespecified subgroups of factors, the HR for Culmerciclib combination therapy was <1 compared with the control group, and the trend of benefit was consistent with that of the main analysis. In particular, the test group PFS benefit was more pronounced in the subgroups of salvage chemotherapy recipients, progesterone receptor (PR)-negative, endocrine primary resistance, low HER2 expression, and visceral metastases.

Safe, controllable and easy to manage[1]

The majority of the most common treatment-related adverse events (TRAEs) with Culmerciclib in combination with Fulvestrant were grade 1-2 and easy to manage; haematological toxicity, such as myelosuppression in grade ≥3, was low; and there were no TRAEs leading to treatment discontinuation or death. Culmerciclib in combination with Fulvestran was generally safe and tolerable.

In July 2024, the new drug application for Culmerciclib in combination with Fulvestrant for the treatment of patients with HR+/HER2- locally advanced or metastatic breast cancer has been filed by the Group with and accepted by the Centre for Drug Evaluation of the National Medical Products Administration of the PRC. In addition, the Group is also advancing phase III clinical study of Culmerciclib for the first-line treatment and adjuvant therapy of HR+/HER2- breast cancer, which is expected to be gradually submitted for marketing application in the next two years, and is expected to provide a safe and effective new treatment option for more HR+/HER2- breast cancer patients.

The Group presented more than 20 latest study results at 2024 CSCO, which comprehensively demonstrated the breakthroughs made by the Group in multiple oncology therapeutic areas. In the future, the Group will continue to focus on innovation and in-depth exploration of innovative drugs and therapeutic solutions, with a view to bringing more benefits to patients and warming more lives with health technology.

Source:

[1] TQB3616 in combination with Fulvestrant for hormone receptor-positive, HER2-negative advanced breast cancer: a randomised, double-blind, parallel-controlled phase III clinical study, 2024 CSCO, 27 September Innovation Session.

By order of the Board
Sino Biopharmaceutical Limited
Tse, Theresa Y Y
Chairwoman

Hong Kong, 27 September 2024

As at the date of this announcement, the Board of the Company comprises six executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y, Mr. Tse Hsin and Mr. Tian Zhoushan, and five independent non-executive directors, namely Mr. Lu Zhengfei, Mr. Li Dakui, Ms. Lu Hong, Mr. Zhang Lu Fu and Dr. Li Kwok Tung Donald.