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

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

VOLUNTARY ANNOUNCEMENT
DATA FROM PHASE II CLINICAL TRIAL OF CULMERCICLIB "CDK2/4/6 INHIBITOR" IN CDK4/6 INHIBITOR-PRETREATED PATIENTS PRESENTED AT 2026 ASCO

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that data from a Phase II clinical trial of culmerciclib "CDK2/4/6 inhibitor" (development code: TQB3616, brand name: 賽坦欣®), a national Category 1 innovative drug independently developed by the Group's subsidiary Chia Tai Tianqing Pharmaceutical Group Co. Ltd. ("**CTTQ**"), was presented at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting. The trial evaluated culmerciclib in patients with prior CDK4/6 inhibitor (CDK4/6i) exposure. Results showed that the culmerciclib combination regimen met its prespecified primary endpoint, demonstrating encouraging antitumor activity and a manageable safety profile, offering a potential new treatment option for patients resistant to prior CDK4/6i.

TQB3616-II-04 (NCT06701818) is a prospective, multicenter, single-arm Phase II trial evaluating the efficacy and safety of culmerciclib plus fulvestrant in patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer who have progressed on prior CDK4/6i combined with endocrine therapy (ET). The primary endpoint is confirmed objective response rate (ORR) assessed by independent review committee (IRC) or investigators. Secondary endpoints include progression-free survival (PFS), clinical benefit rate (CBR), disease control rate (DCR), and safety.

As of April 15, 2026, 35 patients were enrolled, with a median follow-up of 10.8 months. The overall population closely reflected real-world post-resistance characteristics: median age was 56 years, and 71.4% had visceral metastases, including liver (45.7%), lung (45.7%), and brain (5.7%). All patients had received prior CDK4/6i + ET (palbociclib 68.6%, dalpiciclib 28.6%, ribociclib 8.6%; two patients had received two different CDK4/6i). In addition, 37.1% of patients had received prior chemotherapy.

Among 34 evaluable patients, the culmerciclib combination regimen demonstrated potent antitumor activity. The confirmed ORR was 32.4% (95% CI: 17.4–50.5, $p < 0.0001$), meeting the primary endpoint. The DCR was 88.2% (95% CI: 72.6–96.7), and the CBR was 82.4% (95% CI: 65.5–93.2). Median time to response (TTR) was 3.7 months. Notably, median PFS and median duration of response (DoR) have not yet been reached, with a 10-month PFS rate of 61.8% (95% CI: 42.3–76.4), suggesting sustained disease control. These results are clinically meaningful for patients with prior CDK4/6i failure and a high proportion of visceral metastases, suggesting that culmerciclib offers both potent and durable antitumor activity in the resistant setting.

The safety profile was consistent with previous studies, and no new safety signals were observed. Grade ≥3 treatment-related adverse events (TRAEs) occurred in 40.0% of patients. No deaths or discontinuations related to TRAEs were reported. The incidence of grade ≥3 neutropenia, a particular concern with conventional CDK4/6i, was only 5.7%, a finding consistent with the low CDK6 inhibitory activity of culmerciclib. Overall, the regimen demonstrated a manageable safety profile and was well tolerated.

About culmerciclib

Culmerciclib is the world's first oral CDK2/4/6 triple inhibitor, independently developed by CTTQ, with potent inhibitory activity against both CDK4 and CDK2. Its unique mechanism of action offers dual clinical benefits. First, by simultaneously blocking the CDK2 and CDK4 pathways, it may delay or overcome resistance to CDK4/6i monotherapy. Second, compared with conventional CDK4/6i, its favorable low CDK6 inhibitory activity reduces the risk of myelosuppression-related toxicities, thereby improving treatment tolerability.

In December 2025, culmerciclib received approval from China's National Medical Products Administration (NMPA) for use in combination with fulvestrant for the treatment of adult patients with HR+/HER2– locally advanced or metastatic breast cancer who had progressed on prior endocrine therapy. In April 2026, the NMPA approved a new indication for culmerciclib in combination with fulvestrant as first-line endocrine therapy for patients with HR+/HER2– locally advanced or metastatic breast cancer. Currently, culmerciclib is being evaluated as adjuvant therapy for HR+/HER2– breast cancer in a Phase III clinical trial, which has completed patient enrollment.

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

Hong Kong, 2 June 2026

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.