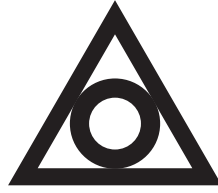


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SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)

Website: www.sbpgroup.com

(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT

**NEW INDICATION OF CULMERCICLIB CAPSULE “CDK2/4/6 INHIBITOR” FOR
FIRST-LINE TREATMENT OF BREAST CANCER APPROVED FOR MARKETING**

The board of directors (the “**Board**”) of Sino Biopharmaceutical Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) announces that culmerciclib capsule “CDK2/4/6 inhibitor” (trade name: 賽坦欣®), in combination with fulvestrant, has received approval for marketing from the National Medical Products Administration (NMPA) of China for the initial endocrine therapy for patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Culmerciclib capsule “CDK2/4/6 inhibitor” is a national Category 1 innovative drug independently developed by the Group’s subsidiary, Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (“**CTTQ**”). This is the second indication approved for marketing of culmerciclib.

The approval of this new indication is primarily based on data from the CULMINATE-2 study. This study is the first Phase III trial worldwide which demonstrates positive results for the combination of CDK2/4/6 inhibitor and endocrine therapy as the first-line treatment for HR-positive/HER2-negative advanced breast cancer, for which the data was first presented as a Late Breaking Abstract (LBA) at the European Society for Medical Oncology (ESMO) Congress 2025 ^[1]:

- The median progression-free survival (mPFS) of culmerciclib in combination with fulvestrant versus placebo combined with fulvestrant were NR (not reached) vs 20.2 months, with a 44% reduction in the risk of disease progression/death (HR=0.56, P=0.0004), as well as significantly higher objective response rate (ORR) and duration of response (DOR) as compared to the control group; in subgroups with poor prognosis, such as visceral metastasis and liver metastasis, the combination regimen of culmerciclib showed a more significant PFS advantage.

- The most common treatment-related adverse events (TRAEs) of the combination regimen of culmenciclib were mostly grade 1-2, which were manageable; the incidence of myelosuppressive toxicity such as grade ≥ 3 neutropenia was only 20.3%, and the incidence of TRAEs leading to discontinuation was only 3.5%. The safety of long-term treatment was controllable and manageable.

Breast cancer is the malignant tumour with the highest incidence among women globally and domestically. In particular, HR-positive/HER2-negative breast cancer is the most common subtype, accounting for approximately 65%–70% of all breast cancer cases^[2]. Authoritative guidelines, such as *Guidelines of Chinese Society of Clinical Oncology (CSCO): Breast Cancer (2025 Edition)*, have recommended the combination of CDK4/6 inhibitors with endocrine therapy as the first-line treatment regimen for HR-positive/HER2-negative advanced breast cancer^[3,4]. However, 30%–40% of patients with metastatic breast cancer still develop resistance shortly after receiving this combination regimen^[5].

Culmenciclib is a global first-in-class CDK2/4/6 inhibitor. By enhancing selective inhibition of CDK2 and CDK4 while reducing inhibition of CDK6, it is expected to delay or overcome resistance mediated by compensatory activation of CDK2 and to achieve a balance between antitumour efficacy and bone marrow safety^[6].

Previously, culmenciclib in combination with fulvestrant for the treatment of HR-positive/HER2-negative breast cancer in patients whose diseases have progressed following prior endocrine therapy was approved for marketing by the NMPA in December 2025. Given its demonstrated clinical value, the regimen has also been included in the *CSCO Breast Cancer Guidelines (2026 Edition)*. Furthermore, the Phase III clinical trial is currently underway to evaluate the combination of culmenciclib with endocrine therapy for the adjuvant therapy of early-stage HR-positive/HER2-negative breast cancer. With the approval of this first-line indication, culmenciclib is expected to offer a new treatment option to a broader patient population by leveraging its clinical potential for deeper response and lower toxicity.

Sources:

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- [3] National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guideline). *Breast Cancer*, version 5. 2023[EB/OL]. [2024-01-12].
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By order of the Board
Sino Biopharmaceutical Limited
Tse, Theresa Y Y
Chairwoman

Hong Kong, 6 May 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.