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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.sinobiopharm.com
(Stock code: 1177)

## VOLUNTARY ANNOUNCEMENT TQC3721 INHALATION SUSPENSION "PDE3/4 INHIBITOR" OBTAINING APPROVAL FOR PHASE III REGISTRATIONAL CLINICAL STUDY FROM CDE

The board of directors (the "Board") of Sino Biopharmaceutical Limited (the "Company", together with its subsidiaries, the "Group") announces that the TQC3721 inhalation suspension "PDE3/4 inhibitor", the category 1 innovative drug developed by the Group, has been approved by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China to commence the phase III registrational clinical study on the maintenance treatment for chronic obstructive pulmonary disease (COPD).

TQC3721 is an inhaled PDE3/4 inhibitor with a new mechanism which has both bronchodilatory and anti-inflammatory effects, thus relieving the patients' symptoms and suppressing inflammation and controlling disease progression. The data from the clinical study shows that among the patients suffering COPD with single bronchodilator and dual bronchodilators as background treatments, TQC3721 significantly improves the bronchodilatory effect and the scoring in St. George's Respiratory Questionnaire, and has better efficacy than drugs with the same target. The relevant data will be presented at an upcoming international academic conference. This phase III clinical study will further observe the efficacy and safety of using TQC3721 inhalation suspension under different background treatments (no background, single bronchodilator or dual bronchodilators) in a larger sample of patients with moderate to severe COPD.

COPD is the third leading cause of death worldwide, causing over 3 million deaths per annum, and has become one of the major challenges in public health globally<sup>[1]</sup>. In China, COPD is one of the chronic respiratory diseases drawing much concern from the state, and it is listed as a key item in terms of prevention and control in the action plan of "Healthy China 2030". As shown by the data, there are approximately 100 million patients suffering COPD in China<sup>[2]</sup>. The currently approved drugs for the treatment of COPD have significant clinical limitations: long-acting bronchodilators (LABA/LAMA)

lack anti-inflammatory effects to stop disease progression though they can relieve symptoms to a certain extent; and in spite of the anti-inflammatory effects of inhaled corticosteroids (ICS), their usage in patients encounters significant limitations, and their applicable population is strictly limited by the GOLD guidelines.

Currently, only one inhaled PDE3/4 inhibitor has been approved for marketing in the world, and TQC3721 ranks the second in the world in terms of its research and development progress. Compared with the existing marketed product, the Phase III clinical trial of TQC3721 will additionally include patients with dual bronchodilators as background treatment, covering a broader range of COPD patients. Moreover, in addition to the inhalation suspension, the inhaled dry powder formulation of TQC3721 is currently in the phase I clinical development stage, which is expected to further improve patient compliance.

## Sources:

- [1] World Health Organization
- [2] Prevalence and risk factors of chronic obstructive pulmonary disease in China (the China Pulmonary Health [CPH] study): a national cross-sectional study. Wang, Chen et al. The Lancet, Volume 391, Issue 10131, 1706 1717.

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

Chairwoman

Hong Kong, 9 June 2025

As of 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.