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
COMPLETION OF ENROLLMENT OF THE FIRST PATIENT IN THE PHASE III CLINICAL TRIAL OF TDI01 "ROCK2 INHIBITOR" FOR IDIOPATHIC PULMONARY FIBROSIS

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the enrollment of the first patient in the Phase III clinical trial for TDI01 "ROCK2 inhibitor" independently developed by the Group for the treatment of idiopathic pulmonary fibrosis (IPF) has been completed, which marks the first highly selective ROCK2 inhibitor to enter the Phase III clinical trial for IPF in the world.

TDI01 is a structurally innovative and hence highly selective ROCK2 kinase inhibitor that precisely targets the angiocrine system – a core hub regulating vascular leakage, fibrosis, inflammation, and immune dysregulation – in order to multidimensionally intervene in the complex pathogenesis of IPF. The highly selective suppression of TDI01 for ROCK2 optimizes the drug safety profile, which is expected to surpass existing standard therapies and deliver clinical benefits.

As shown by the data from the Phase II clinical trial, after 24 weeks of treatment, patients in the TDI01 400mg group achieved an improvement of 89mL in forced vital capacity (FVC) compared to the placebo group. This significantly minimizes the risk of all-cause mortality while effectively minimizing the risk of acute exacerbation and disease progression in IPF. In respect of the safety, the incidence of serious adverse events and the discontinuation rate due to adverse events in the TDI01 treatment group were both lower than those of comparable standard therapies, thus demonstrating the favorable safety and tolerability of TDI01.

IPF is a progressive chronic fibrotic interstitial lung disease with unclear etiology and pathogenesis. As the disease progresses, patients gradually lose their lung function and may ultimately die from respiratory failure due to extensive scarring of lung tissue, under which approximately 3 million people are affected globally[1]. The incidence and prevalence of IPF show an increasing trend on a yearly basis, with the elderly constituting the predominantly affected population. The median survival period of patients is only 2-3 years[2]. However, existing drugs cannot control or reverse already impaired lung function and carry significant adverse reactions such as photosensitivity, liver injury, and diarrhea. There is an urgent clinical need for novel therapies that can comprehensively intervene in complex pathogenesis with superior safety.

TDI01 is a major new drug innovation project under the 13th Five-Year Plan of China. In addition to its indication for IPF, TDI01 is concurrently developed for chronic graft-versus-host disease (cGVHD). In June 2025, it was included in the Breakthrough Therapy Designation (BTD) process by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China for the treatment of moderate to severe cGVHD in patients who have received at least 1 prior line but no more than five prior lines of systemic therapy. The Group will accelerate the clinical development of TDI01, while striving to provide patients with a more effective and safer novel treatment option as soon as possible.

Sources:

[1] Nalysnyk L., et al. Incidence and Prevalence of Idiopathic Pulmonary Fibrosis: Review of the Literature. Eur Respir Rev. 2012;21(126):355-361.

[2] Raghu G., et al. An Official ATS/ERS/JRS/ALAT Statement: Idiopathic Pulmonary Fibrosis: Evidence-based Guidelines for Diagnosis and Management. Am J Respir Crit Care Med. 2011;183:788–824.

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

Hong Kong, 31 December 2025

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.