TransThera Sciences (Nanjing), Inc.
藥捷安康（南京）科技股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2617)

VOLUNTARY ANNOUNCEMENT

GRANT OF TINENGOTINIB (TT-00420) FAST TRACK DESIGNATION FOR TREATMENT OF MCRPC

This announcement is made by TransThera Sciences (Nanjing), Inc. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business advancement and product registration progress of the Group.

The board of directors of the Company (the "**Board**") is pleased to announce that the U.S. Food and Drug Administration (the "**FDA**") has granted the fast track designation of tinengotinib for treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).

mCRPC is a form of advanced prostate cancer. It is defined by disease progression despite ADT, and/or the appearance of new metastases. Prostate cancer remains as the second leading cause of cancer-related mortality among men globally, and mCRPC is the leading cause of death from prostate cancer. With an aging population, the global incidence of mCRPC increased from 180.5 thousand in 2019 to 209.3 thousand in 2024.

Tinengotinib is an internally discovered, global phase III multi-kinase inhibitor that exerts antitumor effects by targeting FGFRs and VEGFRs, mitotic kinases Aurora A/B and Janus kinases (JAK). Ongoing clinical trials in the US and China have revealed the potential of tinengotinib to be efficacious in various solid tumors. It was granted the Orphan Drug Designation (ODD) and Fast Track Designation (FTD) by the FDA for the treatment of CCA, the Breakthrough Therapy Designation (BTD) by NMPA in China, the Orphan Drug Designation (ODD) for the treatment of biliary tract cancer by EMA.

Tinengotinib is the world's first and only investigational drug that has the potential to simultaneously inhibit the FGFR/JAK pathway with clinical evidence in the treatment of mCRPC. In the phase I/II studies of tinengotinib monotherapy, 13 mCRPC patients with measurable disease were enrolled. The overall response rate (ORR) was 46%, and the disease control rate (DCR) was 85%. More than 90% of patients had tumor size reduction and over 60% of patients experienced a more than 30% reduction in tumor volume. Key findings were presented at the 2024 ASCO GU.

As our second fast track designation following the CCA indication, this highlights the consistent execution by our clinical and regulatory teams and the promising efficacy of Tinengotinib that supports further development in the treatment of mCRPC.

By Order of the Board
TransThera Sciences (Nanjing), Inc.
藥捷安康(南京)科技股份有限公司
Dr. Frank Wu
Chairman and Chief Executive Officer

Hong Kong, June 23, 2025

The directors of the Company named in the application to which this announcement relates are: (i) Dr. Frank Wu and Mr. Wu Di as executive directors; (ii) Ms. Jia Zhongxin and Dr. Yi Hua as non-executive directors; and (iii) Mr. Li Shu Pai, Ms. Chui Hoi Yam and Ms. Zheng Zhelan as independent non-executive directors.