Nanjing Leads Biolabs Co., Ltd.
南京维立志博生物科技股份有限公司
(A joint stock company established in the People's Republic of China with limited liability)
(Stock Code: 9887)

VOLUNTARY ANNOUNCEMENT
PHASE III CLINICAL STUDY OF LBL-024 (OPAMTISTOMIG, PD-L1/4-1BB BISPECIFIC ANTIBODY) FOR ADVANCED EXTRAPULMONARY NEUROENDOCRINE CARCINOMA (EP-NEC) APPROVED BY CDE

This announcement is made by Nanjing Leads Biolabs Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform shareholders and potential investors of the Company about the latest business development of the Company.

The Company is pleased to announce that the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of the People's Republic of China has approved the commencement of a confirmatory Phase III clinical study evaluating Opamtistomig (LBL-024, a PD-L1/4-1BB bispecific antibody) in combination with platinum-based chemotherapy as first-line treatment in patients with advanced extrapulmonary neuroendocrine carcinoma (EP-NEC). This approval marks the successful advancement of Opamtistomig's clinical development in EP-NEC from late-line monotherapy to first-line combination therapy — Opamtistomig had previously received CDE approval to conduct a single-arm pivotal registrational clinical study for third-line and beyond EP-NEC patients; the approval of this first-line Phase III study further expands the applicable patient population of Opamtistomig in the EP-NEC setting, fundamentally reshaping the treatment landscape for this cancer type.

The study is a randomized, double-blind, multi-center Phase III clinical study led by Professor Shen Lin (沈琳) of Beijing Cancer Hospital (北京腫瘤醫院) and is being conducted across multiple hospitals in China. The approval of this study is based on the breakthrough efficacy and favorable safety profile demonstrated by Opamtistomig in a Phase Ib/II proof-of-concept study. The study has successfully completed its proof-of-concept trial, and the detailed results are scheduled to be presented at the ESMO Congress this year.

As an integral component of the overall development strategy for Opamtistomig in EP-NEC, the single-arm pivotal registrational clinical study of Opamtistomig as monotherapy for third-line and beyond advanced EP-NEC patients is planned to submit a BLA application in the third quarter of 2026. In addition, the Company is advancing multiple proof-of-concept studies of Opamtistomig and plans to initiate at least two additional Phase III clinical studies, exploring its application across 13 solid tumor indications including first-line NSCLC, first-line BTC, SCLC and ovarian cancer, forming a comprehensive development portfolio covering multiple tumor types and treatment stages. Opamtistomig has demonstrated first-in-class (FIC) or best-in-class (BIC) potential in registrational or Phase II clinical trials across four indications: extrapulmonary neuroendocrine carcinoma (EPNEC), non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC) and biliary tract cancer (BTC).

ABOUT EP-NEC

Neuroendocrine carcinoma (NEC) is a highly proliferative tumor, accounting for approximately 10% to 20% of all neuroendocrine tumors, with the disease arising across multiple organs including the lung, gastrointestinal tract and bladder. NEC can be classified into pulmonary NEC and extrapulmonary NEC (EP-NEC). EP-NEC shares similar characteristics of high invasiveness and metastatic potential with small cell lung cancer (SCLC), with rapid disease progression. The majority of NEC patients are diagnosed at an advanced stage or with distant metastases, and systemic treatment options for NEC are limited, with poor efficacy and unfavorable prognosis.

Currently, the first-line treatment for advanced EP-NEC is primarily platinum-based chemotherapy, with an objective response rate (ORR) of approximately 30% to 50% and a median overall survival (mOS) of approximately one year. After progression on first-line treatment, there is no standard treatment regimen. Second-line treatment options include oxaliplatin-based FOLFOX regimen, irinotecan-based FOLFIRI regimen, CAPTEM ± bevacizumab, or temozolomide monotherapy, with ORR of approximately 10% to 25% and a median overall survival (OS) of approximately 8 months. Therefore, there remains a significant unmet medical need in the treatment of advanced EP-NEC, and effective new therapeutic breakthroughs are urgently needed.

ABOUT LBL-024 (OPAMTISTOMIG)

LBL-024 is a bispecific antibody simultaneously targeting PD-L1 and 4-1BB, and is a pan-tumor IO 2.0 cornerstone therapy with potential survival benefit. Leveraging our self-developed X-body™ platform with full intellectual property rights, LBL-024 achieves conditional activation of 4-1BB, relieving PD-1/PD-L1 immunosuppression while enhancing 4-1BB regulated T-cell activation, achieving a synergistic effect in eliminating tumors. LBL-024 demonstrates a safety profile comparable to PD-1/PD-L1 inhibitors and greater potential for broad-spectrum cancer treatment, and has demonstrated first-in-class (FIC) or best-in-class (BIC) potential in non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), extrapulmonary neuroendocrine carcinoma (EP-NEC) and biliary tract cancer (BTC).

As the first molecule targeting the co-stimulatory receptor 4-1BB to have reached the pivotal single-arm registrational clinical stage globally, LBL-024 has the potential to become the first drug approved for treating EP-NEC. LBL-024 has initiated clinical studies across 13 solid tumor indications in China, including one pivotal registrational clinical study and eight proof-of-concept studies, covering EP-NEC, NSCLC, SCLC, BTC, ovarian cancer (OC), esophageal squamous cell carcinoma (ESCC), hepatocellular carcinoma (HCC), gastric cancer (GC), triple-negative breast cancer (TNBC) and melanoma, among other areas with high unmet medical needs.

4-1BB, as an agonist, can reactivate apoptotic T cells and induce substantial proliferation, making it suitable for treating "cold tumors" that are resistant or unresponsive to PD-1/PD-L1 therapies. LBL-024 received the Breakthrough Therapy Designation (BTD) from CDE of the NMPA in October 2024, as well as the Orphan Drug Designation in treating neuroendocrine carcinoma (NEC) from the FDA in November 2024. In January 2026, LBL-024 received Fast Track Designation (FTD) from the FDA for the treatment of EP-NEC and Orphan Drug Designation from the European Union.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that it will be able to develop, or ultimately market, LBL-024, successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By order of the Board
Nanjing Leads Biolabs Co., Ltd.
南京维立志博生物科技股份有限公司
Dr. KANG XIAOQIANG
Chairman, Executive Director and Chief Executive Officer

Nanjing, PRC, May 18, 2026

As at the date of this announcement, the board of directors of the Company comprises: (i) Dr. Kang Xiaoqiang (Chairman of the Board), Dr. Lai Shoupeng and Mr. Zuo Honggang as executive Directors; (ii) Mr. Zhang Yincheng, Dr. Chen Renhai and Dr. Wu Fenglan as non-executive Directors; and (iii) Dr. Zhang Hongbing, Mr. Du Yilong and Ms. Du Jiliu as independent non-executive Directors.