Junshi Biosciences Announces Primary Endpoints Met in Final Analysis of Phase 3 Study for Perioperative Toripalimab plus Chemotherapy for Resectable Stage Ⅱ-Ⅲ NSCLC

SHANGHAI, China, May 26, 2026 -- Shanghai Junshi Biosciences Co., Ltd (Junshi Biosciences, HKEX: 1877; SSE: 688180), a leading innovation-driven biopharmaceutical company dedicated to the discovery, development, and commercialization of novel therapies, announced that a randomized, double-blind, placebo-controlled, multi-center phase III clinical study ("NEOTORCH", NCT04158440) of the company's product toripalimab in combination with platinum-containing doublet chemotherapy as perioperative treatment for resectable stage II-III non-small cell lung cancer ("NSCLC") patients has finished its final analysis. The primary endpoints of event-free survival ("EFS") and major pathological response ("MPR") rate in the stage II-III population, as well as the MPR rate in the stage III population, met the pre-defined efficacy boundary. Junshi Biosciences now plans to submit a supplemental new drug application ("sNDA") for the product to regulatory authorities in the near future. Toripalimab combined with chemotherapy has already been approved for perioperative treatment of patients with resectable stage III NSCLC, and this new sNDA will aim to expand the approval to perioperative treatment of resectable stage II-III NSCLC.

Lung cancer is a malignant tumor with the highest prevalence and mortality rate in the world. According to data released by GLOBOCAN, in 2022, 1.06 million new lung cancer cases were reported in China, accounting for 22.0% of the nation's new cancer cases; in the same year, China also reported 0.73 million lung cancer deaths, representing 28.5% of cancer deaths nationwide. Amongst these cases, 20%-25% were surgically resectable at first diagnosis, but even after radical surgical treatment, 30%-55% of the patients suffered from post-surgical recurrence and death. Radical surgery in combination with chemotherapy is one way to prevent recurrence, but chemotherapy, as preoperative neoadjuvant or postoperative adjuvant therapy, has limited clinical benefits and can only raise the 5-year survival rate by approximately 5%.

Recently, immunotherapy represented by PD-(L)1 inhibitors has been transforming the landscape of cancer treatment. PD-(L)1 inhibitors have displayed long-term effects in tumor control and/or elimination. Tumor cells exploit the PD-1 and PD-L1/PD-L2 binding process, but PD-(L)1 inhibitors stop immune evasion and suppression, reactivating the patients' own immune cells to kill the tumor. Many authoritative lung cancer treatment guidelines both domestically and internationally recommend PD-(L)1 inhibitors as one of the standard perioperative treatments for resectable stage II-III NSCLC.

NEOTORCH is a randomized, double-blind, placebo-controlled phase III clinical study aiming to compare the efficacy and safety of toripalimab or placebo in combination with chemotherapy as perioperative treatment for resectable stage II/III NSCLC patients. Led by principal investigator Professor Shun LU of Shanghai Chest Hospital, School of Medicine, Shanghai Jiao Tong University, the study enrolled a total of 501 patients with resectable stage II-III NSCLC. The primary endpoints are EFS in patients with stage III and stage II-III disease as assessed by researchers, and MPR rate in patients with stage III and stage II-III disease as assessed by the Blind Independent Pathology Review Committee (BIPR). The secondary endpoints include OS, EFS as assessed by the Independent Review Committee (IRC), pathological complete remission rate (pCR rate), disease-free survival (DFS) and safety.

In January 2023, the EFS interim analysis of patients with resectable stage III NSCLC of NEOTORCH met the primary endpoint. The latest study results were presented through oral presentation at the April 2023

session of the American Society of Clinical Oncology (ASCO) Plenary Session and the 2023 ASCO Annual Meeting. NEOTORCH was the world's first phase 3 clinical study of an anti-PD-1 monoclonal antibody for NSCLC perioperative treatment (including neoadjuvant and adjuvant) with positive EFS results published in *the Journal of the American Medical Association* (*JAMA*) in January 2024.

The results showed that compared to perioperative chemotherapy alone, toripalimab in combination with chemotherapy as perioperative treatment led to a significant improvement in EFS (median EFS: not reached vs. 15.1 months, P<0.001), reduced risk of disease recurrence, progression events or death by 60% (HR=0.40, 95% CI: 0.28-0.57). Meanwhile, the OS in the toripalimab in combination with chemotherapy group showed a clear trend toward improved outcomes (HR=0.62, 95% CI: 0.38-1.00). Moreover, toripalimab in combination with chemotherapy as perioperative treatment increased the pCR rate to nearly 25-fold (pCR rate: 24.8% vs. 1.0%) and the MPR rate to nearly 6-fold (MPR rate: 48.5% vs. 8.4%). The primary endpoint of the final analysis will be presented at an upcoming international academic conference.

In December 2023, based on the NEOTORCH interim analysis results, the supplemental new drug application for the new indication of toripalimab in combination with platinum-containing doublet chemotherapy for perioperative treatment of resectable stage IIIA-IIIB NSCLC patients was approved by the NMPA. It was the first domestically approved perioperative therapy for lung cancer in China, and the second worldwide.

About Toripalimab

Toripalimab is an anti-PD-1 monoclonal antibody developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2, and to induce PD-1 receptor internalization (endocytosis function). Blocking PD-1 interactions with PD-L1 and PD-L2 promotes the immune system's ability to attack and kill tumor cells.

More than forty company-sponsored toripalimab clinical studies covering more than fifteen indications have been conducted globally by Junshi Biosciences, including in China, the United States, Europe and Southeast Asia. Ongoing or completed pivotal clinical trials evaluating the safety and efficacy of toripalimab cover a broad range of tumor types, including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney, and skin.

In the Chinese mainland, toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing (approved in China as TUOYI®). Currently, there are twelve approved indications for toripalimab in the Chinese mainland:

1. unresectable or metastatic melanoma after failure of standard systemic therapy;
2. recurrent or metastatic nasopharyngeal carcinoma (NPC) after failure of at least two lines of prior systemic therapy;
3. locally advanced or metastatic urothelial carcinoma (UC) that failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy;

4. in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic NPC;
5. in combination with paclitaxel and cisplatin in first-line treatment of patients with unresectable locally advanced/recurrent or distant metastatic esophageal squamous cell carcinoma (ESCC);
6. in combination with pemetrexed and platinum as the first-line treatment in EGFR mutation-negative and ALK mutation-negative, unresectable, locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC);
7. in combination with chemotherapy as perioperative treatment and subsequently with monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage IIIA-IIIB NSCLC;
8. in combination with axitinib for the first-line treatment of patients with medium to high risk unresectable or metastatic renal cell carcinoma (RCC);
9. in combination with etoposide plus platinum for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC);
10. in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic triple-negative breast cancer (TNBC);
11. in combination with bevacizumab for the first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) patients;
12. first-line treatment for unresectable or metastatic melanoma;
13. in combination with disitamab vedotin for the first-line treatment of HER2-expressing UC.

The first 12 indications have been included in the National Reimbursement Drug List (NRDL) (2025 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma, RCC and TNBC. Toripalimab for the treatment of advanced NPC and ESCC was approved in Hong Kong SAR, China.

Internationally, toripalimab has been approved for marketing in more than 40 countries and regions including the United States, the European Union, India, the United Kingdom, Australia and Singapore, and is also under review for marketing in various countries and regions worldwide.

About Junshi Biosciences

Founded in December 2012, Junshi Biosciences (HKEX: 1877; SSE: 688180) is an innovation-driven biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapeutics. With our outstanding capacity for innovative drug discovery, strong biotechnology R&D capability, and large-scale production capacity, we have successfully developed a drug candidate portfolio with global competitiveness and a well-structured research pipeline, which

covers therapeutic areas including cancer, autoimmune, metabolic, and infectious diseases. Our innovative field spans cutting-edge therapeutic modalities, including mAbs, small-molecule drugs, ADCs, bsAb/msAb, fusion proteins, nucleic acid drugs and vaccines. Five of the company's products have received marketing authorizations in China and international markets, one of which is toripalimab, China's domestically developed anti-PD-1 monoclonal antibody. Toripalimab has been approved in over 40 countries and regions including China, the US, and Europe.

With a mission of "providing patients with world-class, trustworthy, affordable, and innovative drugs," Junshi Biosciences is "In China, For Global." At present, the company boasts nearly 3,000 employees mainly in the United States (Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou). For more information, please visit: http://www.junshipharma.com.

Junshi Biosciences Contact Information

IR Team:

Junshi Biosciences

info@junshipharma.com

+ 86 021-6105 8800

PR Team:

Junshi Biosciences

Zhi Li

zhi_li@junshipharma.com

+ 86 021-6105 8800