Junshi Biosciences Announces Acceptance of the Supplemental Application for Toripalimab plus Chemotherapy as Perioperative Treatment for Resectable Stage Ⅱ-Ⅲ NSCLC

SHANGHAI, China, July 21, 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 the supplemental application for toripalimab in combination with platinum-containing chemotherapy as perioperative treatment and subsequent monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage II-III non-small cell lung cancer (NSCLC) has been accepted by the National Medical Products Administration (NMPA). The supplemental application expands toripalimab's indication from adult patients with resectable stage IIIA-IIIB NSCLC to adult patients with 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 the National Clinical Research Center for Cancer, in 2024, there were approximately 1.18 million new lung cancer cases and 0.74 million lung cancer deaths in China, accounting for 22.83% of all new cancer cases and 28.79% of all cancer deaths in the nation. 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 improve the 5-year survival rate by around 5%.

Immunotherapy, with PD-(L)1 inhibitors at the forefront, has been transforming the landscape of cancer treatment. It has long-term effects in terms of tumor control and/or elimination by relieving the immune suppression of tumor cells and reactivating the patients' own immune cells to kill cancer. Many local and international lung cancer treatment guidelines recommend PD-(L)1 inhibitors as one of the standard perioperative treatments for resectable stage II-III NSCLC.

The supplemental application is principally based on NEOTORCH (NCT04158440), a randomized, double-blind, placebo-controlled phase 3 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 event-free survival (EFS) in patients with stage III and stage II-III disease as assessed by researchers, and major pathological response (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 overall survival (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 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%).

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.

In May 2026, the NEOTORCH finished the final analysis. The primary endpoints of EFS and 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.

In July 2026, the full results of a post hoc analysis of surgical outcomes from the NEOTORCH of toripalimab in combination with chemotherapy for perioperative treatment of resectable stage III NSCLC patients were officially published in *JAMA Surgery*, a leading international journal in the field of surgery. The analysis focused on stage III NSCLC patients who underwent surgery in the NEOTORCH and systematically evaluated the effects of toripalimab in combination with chemotherapy as perioperative treatment on surgical feasibility, complications, survival and other outcomes.

The results demonstrated that toripalimab in combination with chemotherapy significantly reduced the surgery cancellation rate (17.8% vs. 26.7%; p=0.03), thereby enabling more patients to undergo surgical resection without increasing perioperative risks or giving rise to any new safety signals. Among the 314 patients who completed surgery, compared with placebo in combination with chemotherapy, toripalimab in combination with chemotherapy effectively achieved higher rates of tumor downstaging and lymph node downstaging (tumor downstaging rate: 80.7% vs. 50.7%, lymph node downstaging rate: 67.5% vs. 48.6%), and improved the EFS benefit of the patients (HR=0.50, 95% CI: 0.33-0.74; p < 0.001). Among the patients who achieved tumor downstaging or lymph node downstaging, toripalimab in combination with chemotherapy significantly improved EFS compared with placebo in combination with chemotherapy (HR=0.45 for both, p=0.002 and p=0.009).

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 nearly 50 countries and regions including the United States, the European Union, India, the United Kingdom, Australia, Singapore, Malaysia and South Africa, 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 nearly 50 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