Junshi Biosciences Announces Final Analysis Results of the Phase 3 NEOTORCH Study at ESMO Congress 2026

- *Perioperative toripalimab plus chemotherapy demonstrated significant and durable improvements in event-free survival and overall survival in patients with resectable stage II-III non-small cell lung cancer.*

SHANGHAI, China, October 27, 2026 (GLOBE NEWSWIRE) -- 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 final analysis results from the Phase 3 NEOTORCH study (NCT04158440) were presented during an oral session at the 2026 European Society for Medical Oncology (ESMO) Congress (Abstract No. LBA64) and simultaneously published in *Annals of Oncology*. Professor Shun LU and Professor Ziming LI from Shanghai Chest Hospital, Shanghai Jiao Tong University School of Medicine served as the corresponding author and first author of the publication, respectively.

NEOTORCH (NCT04158440) is a randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating perioperative toripalimab in combination with chemotherapy in patients with resectable stage II-III non-small cell lung cancer (NSCLC). A total of 501 patients were randomized 1:1 to receive toripalimab (240 mg, Q3W) or placebo, each in combination with chemotherapy for three cycles before surgery and one cycle after surgery, followed by up to 13 cycles of toripalimab or placebo maintenance therapy.

With a median follow-up of 48.2 months, perioperative toripalimab in combination with chemotherapy demonstrated significant and durable improvements in event-free survival (EFS), major pathological response (MPR), and overall survival (OS) compared with placebo plus chemotherapy in patients with resectable stage II-III NSCLC. The safety profile was manageable, with no new safety signals identified.

Key Results

At the prespecified final analysis, with a median follow-up of 48.2 months:

- **EFS:** Toripalimab plus chemotherapy significantly prolonged EFS compared with placebo plus chemotherapy (HR=0.52; 95% CI: 0.39-0.68; P<0.0001), representing a 48% reduction in the risk of disease recurrence, progression, or death. Median investigator-assessed EFS was not reached in the toripalimab arm versus 20.2 months in the placebo arm. The EFS benefit was generally consistent across key patient subgroups, including disease stage, PD-L1 expression, histology, and age.
- **Pathological response:** The blinded independent pathologic review (BIPR)-assessed MPR rate was 47% versus 9% in the toripalimab and placebo arms, respectively, and the pathologic complete response (pCR) rate was 26% versus 1% (both P<0.0001).

- **OS:** Toripalimab plus chemotherapy significantly improved OS versus placebo plus chemotherapy (HR=0.66; 95% CI: 0.49-0.89; P=0.0072), corresponding to a 34% reduction in the risk of death. Median OS was not reached in either treatment arm.
- **Safety:** The safety profile remained manageable and consistent with prior analyses, with no new safety signals identified.

The prespecified interim analysis of NEOTORCH in patients with resectable stage III NSCLC previously demonstrated statistically significant improvements in EFS and MPR. The results were presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting and published in *JAMA* in January 2024.

Based on these interim results, in December 2023, China's National Medical Products Administration (NMPA) approved toripalimab in combination with platinum-based chemotherapy for the perioperative treatment of patients with resectable stage IIIA-IIIB NSCLC. In July 2026, the NMPA accepted a supplemental application to expand the indication to patients with resectable stage II-III NSCLC, based on the final analysis of the overall study population.

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 over 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 over 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." The company currently employs more than 3,000 people worldwide. Headquartered in Shanghai, China, it has a business presence in multiple countries and regions around the world. For more information, please visit: http://www.junshipharma.com.

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