Junshi Biosciences Announces Approval of Toripalimab NDA for the 1st-line treatment of HER2 Expressing Urothelial Carcinoma

SHANGHAI, China, May 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 new drug application (NDA) for toripalimab in combination with disitamab vedotin for patients with HER2-expressing (which is defined as achieving a score of 1+, 2+ or 3+ in HER2 immunohistochemistry test), locally advanced or metastatic urothelial carcinoma (UC) was approved by the National Medical Products Administration (NMPA). Disitimab vedotin is an antibody drug conjugate independently developed by RemeGen Co., Ltd. With this latest approval, toripalimab injection now has 13 approved indications in the Chinese Mainland.

UC is among the top ten most prevalent malignant tumors in the world, and in China, its incidence and mortality rates continue rising. According to the latest data from the National Cancer Center, in 2022, the number of new cases of UC in China reached 92,900, and the number of deaths exceeded 40,000. UC is a serious threat to the life and health of patients, and there are huge unmet clinical needs.

In 2021, toripalimab injection was approved for the second-line and above treatment of advanced UC, becoming the first immunotherapy drug approved for non-selective population-based indications of advanced UC in China.

The approval of this new indication is based on results from the RC48-C016 study (NCT05302284). The study is a multi-center, randomized, open-label and controlled phase 3 clinical trial which evaluated the efficacy and safety of toripalimab in combination with disitamab vedotin versus gemcitabine in combination with cisplatin/carboplatin in systemic-treatment-naive patients with HER2 (human epidermal growth factor receptor 2)-expressing (which is defined as HER2 IHC 1+, 2+ or 3+) locally advanced or metastatic UC. The study was conducted in 74 clinical centers across China with Professor Jun GUO from Beijing Cancer Hospital and Professor Aiping ZHOU from the Cancer Hospital of the Chinese Academy of Medical Sciences as the principal investigators.

In October 2025, the study results of RC48-C016 were published in *The New England Journal of Medicine* (*NEJM*), and shared in an oral presentation at the Presidential Symposium of the 2025 European Society for Medical Oncology (ESMO) annual meeting (#LBA7).

The results were positive for both primary endpoints, progression free survival ("PFS", assessed by blinded independent review) and overall survival ("OS"). Compared with traditional chemotherapy, toripalimab in combination with disitamab vedotin for the first-line treatment of HER2-expressing advanced UC more than doubled the median PFS [13.1 months vs. 6.5 months, hazard ratio (HR)=0.36, 95%CI: 0.28-0.46; p<0.0001], as well as the median OS (31.5 months vs. 16.9 months, HR=0.54, 95%CI: 0.41-0.73; p<0.0001). The objective response rate (ORR) greatly increased (76.1% vs. 50.2%) and the medium duration of response (DoR) almost tripled in comparison (14.6 months vs. 5.6 months). The combination therapy group also demonstrated significant improvements in safety compared to the chemotherapy group.

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, said, "The approval of toripalimab's 13th indication is a huge milestone for us all, and sheds light on the importance of our open collaboration R&D strategy. In urologic oncology immunotherapy, toripalimab continues to be a driving force and this approval deepens its impact across the immunotherapy landscape. We are immensely proud to partner with RemeGen. Together, we were able to combine two locally-developed innovations to create a

powerful synergistic treatment that significantly improves both PFS and OS. Moving forward, Junshi Biosciences will expand on our Immuno-Oncology (I-O) 2.0 strategy, pursuing the next generation of combination therapies and novel target drugs to fulfill our commitment to enduring innovation, ensuring China's innovation benefits global patients."

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.

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