Junshi Biosciences Announces the Acceptance of the sNDA for Toripalimab as the 1st-line Treatment of HER2-expressing Urothelial Carcinoma

SHANGHAI, China, Aug 8, 2025 -- 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 new drug application ("sNDA") for toripalimab (trade name: TUOYI®) in combination with disitamab vedotin, an antibody-drug conjugate ("ADC") developed by RemeGen Co., Ltd. as the treatment of HER2-expressing (HER2 expression is defined as a HER2 immunohistochemistry test result of 1+, 2+, or 3+) locally advanced or metastatic urothelial carcinoma ("UC") has been accepted by the National Medical Products Administration ("NMPA"). This is toripalimab's 13th application for marketing submitted in the Chinese mainland.

UC is one of the ten most prevalent malignant tumors in the world, and in China, its incidence and mortality rates continue rising annually. 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 reached over 40,000. UC is a serious threat to the life and health of patients, and there are huge unmet clinical needs.

In 2021, toripalimab 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. Over the past 5 years, the emergence of PD-(L)1 monoclonal antibodies and novel ADCs has been continuously reshaping the treatment landscape for advanced UC. Compared with conventional chemotherapy, novel therapies have demonstrated significant improvements in terms of survival benefit and tolerability, leading to more diverse and precise treatment options for patients.

The sNDA is based on results from the RC48-C016 study (NCT05302284), 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 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 May 2025, the primary endpoints of progression-free survival ("PFS", based on independent radiographic review) and overall survival ("OS") of the RC48-C016 study met the pre-defined efficacy boundary. The results showed that in HER2-expressing, locally advanced or metastatic UC, toripalimab in combination with disitamab vedotin as a first-line treatment significantly improved PFS and OS compared to gemcitabine in combination with cisplatin/carboplatin. Toripalimab has a good safety profile that is consistent with previous studies, with no new safety signals identified. Further details will be presented at major international academic conferences.

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 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.

The first 10 indications have been included in the National Reimbursement Drug List (NRDL) (2024 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma, perioperative treatment of NSCLC, treatment of RCC and treatment of TNBC. In October 2024, toripalimab for the treatment of recurrent or metastatic NPC was approved in Hong Kong SAR, China.

Internationally, toripalimab has been approved for marketing in the United States, the European Union, India, the UK, Jordan, Australia, Singapore, United Arab Emirates, Kuwait and other countries and regions. In addition, toripalimab BLAs are under review in many countries or regions around the globe.

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. The company has established a diversified R&D pipeline comprising over 50 drug candidates, with five therapeutic focus areas covering cancer, autoimmune, metabolic, neurological, and infectious diseases. Five of the company's products have received approvals in China and international markets, one of which is toripalimab, China's first domestically produced and independently developed anti-PD-1 monoclonal antibody. Toripalimab has been approved in 40 countries and regions including China, the US, and Europe. During the COVID-19 pandemic, Junshi Biosciences actively shouldered the social responsibilities of a Chinese pharmaceutical company through its involvement in developing etesevimab, MINDEWEI®, and other novel therapies for the prevention and treatment of COVID-19.

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 approximately 2,500 employees in the United States (Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc.). For more information, please visit: http://www.junshipharma.com.

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