**Junshi Biosciences Announces the sNDA Approval of Toripalimab for the 1st-line Treatment of Melanoma**

SHANGHAI, China, April 25, 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 (“NDA”) for toripalimab (trade name: TUOYI®) as the first-line treatment for unresectable or metastatic melanoma has been approved by the National Medical Products Administration (“NMPA”). This marks the approval of toripalimab’s 12th indication in the Chinese mainland.

Melanoma is the most malignant type of skin cancer. According to GLOBOCAN 2022 statistics, approximately 332,000 new melanoma cases and 59,000 deaths were recorded globally that year. Though melanoma is relatively uncommon in China, its mortality rate is high (approximately 5,000 deaths amongst approximately 9,000 new cases in 2022) and its incidence rate is rising year by year. Since 2018, anti-PD-1 monoclonal antibodies have been approved for the second-line or later treatment of advanced melanoma in China and are widely used clinically. However, the first-line standard treatment for advanced melanoma is still dominated by traditional chemotherapy or targeted therapy (limited to patients with BRAF V600 mutation). Until now, no domestic anti-PD-1 monoclonal antibody had been approved for advanced melanoma in China, creating an urgent clinical need for first-line immunotherapy options.

The supplemental NDA approval is based on data from the MELATORCH study (NCT03430297). MELATORCH is a multicenter, randomized, open-label, positive-controlled Phase 3 clinical study, and is also the first pivotal registrational clinical study of a PD-(L)1 inhibitor as the first-line treatment for advanced melanoma that has yielded positive results. Led by Professor Jun GUO from Peking University Cancer Hospital as the Principal Investigator, the study was conducted in 11 clinical centers across the country. The study was designed to compare the efficacy and safety of toripalimab versus dacarbazine for the systemic anti-tumor treatment-naive patients with unresectable or metastatic melanoma.

Prior to this, the results of the MELATORCH study made its debut at the 27th National Clinical Oncology Conference and 2024 Chinese Society of Clinical Oncology (CSCO) Annual Meeting. The results showed that compared with the dacarbazine group (N=128), the progression-free survival (“PFS”) assessed by Blinded Independent Central Review (BICR) of the toripalimab group (N=127) was significantly prolonged, with the median PFS of the two groups being 2.3 months vs. 2.1 months respectively, and the disease progression or mortality risk was reduced by 29.2% (hazard ratio [HR]=0.708, 95% CI: 0.526-0.954; P=0.0209). The sensitivity analysis of median overall survival (“OS”), corrected for the impact of subsequent anti-tumor treatment, showed that compared with the dacarbazine group, the toripalimab treatment group showed a significant trend towards survival benefit, with the median OS being 15.1 months vs. 9.4 months (HR=0.680, 95% CI: 0.486-0.951) respectively. Toripalimab has a good safety profile that is consistent with previous studies with no new safety signals identified.

Professor Jun GUO from Peking University Cancer Hospital said, “Melanoma is a highly aggressive cancer. Due to its low sensitivity to traditional radiotherapy and chemotherapy, patients are often faced with poor survival outcomes. However, thanks to melanoma’s high immunogenicity, immunotherapies such as toripalimab have significantly improved patient survival in recent years. In China, advanced melanoma patients—including those in second-line and later—have gained broad access to these treatments through national medical insurance. Now, toripalimab has been extended to first-line treatment of advanced melanoma. Compared to traditional chemotherapy, toripalimab has demonstrated significant advantages in PFS, ORR, and DoR, as well as a clear trend toward improved OS. Notably, this approval was based on the MELATORCH study, which exclusively enrolled Chinese patients. The trial design aligned closely with clinical practice in China, and thus the findings were more relevant to Chinese melanoma patients. We hope that China’s independently developed immunotherapies like toripalimab can provide a comprehensive treatment solution for advanced melanoma and offer new hope to more patients.”

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, also shared her enthusiasm: “Within a month, toripalimab has secured approvals for two new indications—liver cancer and melanoma. This milestone achievement was, without a doubt, made possible by the selfless and dedicated collaboration of researchers, participating patients, and R&D teams. Seven years ago, toripalimab had just pioneered breakthroughs in second-line melanoma treatment, becoming China’s first domestically developed anti-PD-1 monoclonal antibody and starting a new era of immunotherapy in China; today, toripalimab is again reaching new heights as it becomes the first Chinese-developed first-line immunotherapy for melanoma. Not only does this demonstrate toripalimab’s exceptional clinical value, it also reflects China’s growing strength and innovation in immuno-oncology. Moving forward, we will remain committed to advancing world-class therapies to benefit patients across the world!”

**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 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 over 35 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.

**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