Junshi Biosciences Announces Approval of sNDA for Toripalimab in Combination with Bevacizumab for 1st-line Treatment of Advanced Hepatocellular Carcinoma

SHANGHAI, China, March 21, 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 National Medical Products Administration ("NMPA") has approved the supplemental new drug application ("sNDA") for the company's product, toripalimab, in combination with bevacizumab for the first-line treatment of unresectable or metastatic hepatocellular carcinoma ("HCC") patients.

Globally, liver cancer is a common malignant tumor of the digestive system, and the main pathological type is HCC (accounting for about 90%). According to data released by the GLOBOCAN for 2022, the annual number of new cases and deaths of liver cancer worldwide was 866,000 and 759,000, respectively. China has a high incidence of liver cancer. In 2022, the number of new liver cancer cases reached 368,000 (accounting for 42.4% of global cases), ranking fourth among domestic malignant tumors, with 317,000 deaths (accounting for 41.7% of global cases), ranking second among domestic malignant tumors. Due to its insidious onset, about 70%-80% of liver cancer patients in China are already at the intermediate or advanced stage at first diagnosis, with a median overall survival ("OS") of only approximately 10 months and a five-year survival rate of approximately 12%.

The supplemental NDA approval is based on data from the HEPATORCH study (NCT04723004), which is a multinational multi-center, randomized, open-label, active-controlled phase 3 clinical study. Professor Jia FAN, an academician of the Chinese Academy of Sciences, from Zhongshan Hospital affiliated to Fudan University, served as the principal investigator. HEPATORCH was launched in 57 clinical centers in the Chinese mainland, China's Taiwan and Singapore, and a total of 326 patients were enrolled. The study aimed to evaluate the efficacy and safety of toripalimab in combination with bevacizumab for the first-line treatment of unresectable or metastatic HCC compared to the standard treatment with sorafenib.

In September 2024, the results of the HEPATORCH study made its debut at the 27th National Clinical Oncology Conference and 2024 Chinese Society of Clinical Oncology (CSCO) Academic Annual Meeting. The results of the study showed that the primary endpoints, progression-free survival ("PFS," based on independent radiographic review) and OS, both achieved positive results.

HEPATORCH demonstrated that compared with sorafenib, toripalimab in combination with bevacizumab could significantly extend the PFS and OS of patients, with a median PFS of 5.8 months vs. 4.0 months, reduce the risk of disease progression or death by 31% (hazard ratio [HR]=0.69, 95% CI: 0.525-0.913; P=0.0086), with a median OS of 20.0 months vs. 14.5 months, and reduce the risk of death by 24% (HR=0.76, 95% CI: 0.579-0.987; P=0.0394). The objective response rate ("ORR") of the toripalimab and bevacizumab group was significantly higher than that of the sorafenib group. The ORR of the two groups were 25.3% and 6.1%, respectively. Furthermore, the combination therapy has a good safety profile in patients with advanced HCC. The toxicity spectrum is consistent with the known toxicity spectrum of the standard monotherapy, and no new safety signal was identified.

Academician Jia FAN from Zhongshan Hospital affiliated with Fudan University said, "The combination of immunotherapy and anti-angiogenic therapy has become the foundation of first-line treatment for

advanced liver cancer. The HEPATORCH study has fully demonstrated the clinical efficacy of toripalimab in liver cancer patients in China, achieving an ORR of 25.3%, a median PFS of 5.8 months, and a median OS of 20.0 months. The 'TB' regimen combining toripalimab with bevacizumab will benefit many advanced liver cancer patients in China."

Dr. Jianjun ZOU, Junshi Biosciences' General Manager and CEO said, "Building on the success of our previously approved 10 indications—the 'Perfect 10,' toripalimab has reached another breakthrough achievement with the official approval of its 11th indication, and we are extremely elated! China has suffered the brunt of liver cancer, and Chinese patients have long faced the challenge of limited treatment options. Junshi Biosciences consistently prioritizes the clinical needs of liver cancer treatment around the world, advancing clinical research through combination strategies tailored to patients across the different stages of disease progression. Our goal is to provide more precise and diverse treatment options for liver cancer patients. Moving forward, we remain dedicated to liver cancer innovation and integrating even greater 'Chinese Wisdom' into the fight against this disease."

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 eleven 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.

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 and other countries and regions. In addition, toripalimab BLAs are under reviews in many countries or regions around the global.

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 (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc.). For more information, please visit: http://www.junshipharma.com.

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