Junshi Biosciences Announces Approval of the sNDA for Toripalimab for the 1st-Line Treatment of Renal Cancer

SHANGHAI, China, April 7, 2024 -- 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 toripalimab (product code: JS001) in combination with axitinib for the first-line treatment of patients with medium to high risk unresectable or metastatic renal cell carcinoma ("RCC"). This is the first approved immunotherapy for renal carcinoma in China.

Renal carcinoma is the third most common malignancy of the urinary system globally, and RCC accounts for 80%~90% of all cases of renal carcinoma. There were approximately 77,000 new cases of and 46,000 deaths due to renal carcinoma in China in 2022. Distant metastasis occurred in about one-third of renal carcinoma patients at initial diagnosis, and in 20%-50% of localized patients after nephrectomy. According to the risk classification of the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), the median overall survival ("OS") of patients with low, medium and high risk metastatic RCC receiving anti-vascular targeted treatment were 35.3, 16.6 and 5.4 months, respectively. Therefore, compared to low-risk patients, the clinical needs for new treatment options are more urgent for patients with medium and high risk advanced RCC.

The approval of the sNDA is mainly based on data from the RENOTORCH study (NCT04394975), a multi-center, randomized, open-label, active-controlled Phase 3 clinical study led by principal investigators Professor Jun GUO from Peking University Cancer Hospital and Professor Yiran HUANG from Renji Hospital Affiliated to Shanghai Jiao Tong University School of Medicine. The study was conducted across 47 medical centers, and represents the first pivotal Phase 3 clinical study of immunotherapy for patients with advanced RCC in China.

A total of 421 randomized patients with medium to high risk unresectable or metastatic RCC were enrolled in the study and randomly assigned in a 1:1 ratio to receive toripalimab in combination with axitinib (n=210) or sunitinib alone (n=211). The primary endpoint is progression free survival ("PFS") as assessed by the Independent Review Committee ("IRC"), and secondary endpoints include PFS as assessed by investigators, objective response rate ("ORR") as assessed by IRC or investigators, duration of response ("DoR"), disease control rate (DCR), OS, safety profile, etc.

Previously, the study results of RENOTORCH made its debut at the Proffered Paper Session of the European Society for Medical Oncology (ESMO) congress 2023. The full text was simultaneously published in *Annals of Oncology*, the official journal of ESMO. The study data showed that, based on the assessment results of IRC, compared with sunitinib monotherapy, toripalimab in combination with axitinib for the treatment significantly prolonged the PFS of patients by nearly twofold (median PFS: 18.0 vs. 9.8 months, P=0.0028), and the risk of disease progression or death was reduced by 35% (hazard ratio [HR]=0.65; 95% CI: 0.49, 0.86). In addition, the ORR was higher (56.7% vs. 30.8%, P<0.0001) and the DoR was longer (median DoR: not reached vs 16.7 months; HR=0.61) in the toripalimab group. The OS of the toripalimab group also showed a clear trend of benefit (median OS: not reached vs 26.8 months), and the risk of death was reduced by 39% (HR=0.61; 95%CI: 0.40, 0.92). In terms of safety, toripalimab in combination with axitinib demonstrated a favorable safety and tolerability profile, and no new safety

signals were observed.

“From a global perspective, targeted therapy in combination with immunotherapy has become the standard treatment approach for advanced RCC,” said Professor Jun GUO from Peking University Cancer Hospital. “However, no such treaments have been approved in China. The approval of toripalimab’s new indications opens a new chapter in combined targeted therapy and immunotherapy in China, and it will transform current clinical practices for advanced RCC and introduce new treatment options for medium to high-risk patients!”

“The treatment methods for advanced RCC are limited, especially for medium to high risk patients, who often face suboptimal prognoses,” said Professor Yiran HUANG from Renji Hospital Affiliated to Shanghai Jiao Tong University School of Medicine “The approval of toripalimab combined with axitinib addresses the gap in first-line immunotherapy for renal cancer in China. Compared to targeted monotherapy, toripalimab combined with targeted therapy will significantly improve patients’ PFS, offering promising prospects for many advanced RCC patients in China.”

“Thank you to all medical professionals, patients, and R&D personnel involved in the RENOTORCH study for their contributions,” said Dr. Jianjun ZOU, CEO of Junshi Biosciences. “Their dedication has led to a pioneering breakthrough in renal cancer, first of its kind in China! Junshi Biosciences will remain committed to addressing domestic clinical needs and continue investing in research and development to help patients live longer and better!”

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 for enhanced 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, Southeast Asia, and Europe. 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 China, toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing (approved in China as TUOYI®). Currently, there are eight approved indications for toripalimab in China:

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 RCC.

The first six indications have been included in the National Reimbursement Drug List (NRDL) (2023 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma.

In the United States, the U.S. FDA has approved the Biologics License Application for toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for toripalimab, as a single agent, for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy in October 2023. The FDA has granted toripalimab 2 Breakthrough Therapy designations for the treatment of NPC, 1 Fast Track designation for the treatment of mucosal melanoma, and 5 Orphan Drug designations for the treatment of esophageal cancer, NPC, mucosal melanoma, soft tissue sarcoma, and small cell lung cancer (SCLC).

In Europe, marketing authorization applications (MAA) were accepted by the European Medicines Agency (EMA) and the MHRA for 1) toripalimab combined with cisplatin and gemcitabine for the first-line treatment of patients with locally recurrent or metastatic NPC and 2) toripalimab combined with paclitaxel and cisplatin for the first-line treatment of patients with unresectable locally advanced/recurrent or metastatic ESCC, in December 2022 and February 2023.

In Australia, the new chemical entity (NCE) application was accepted by the Australia Therapeutic Goods Administration ("TGA") in November 2023. The TGA has also granted toripalimab an Orphan Drug designation for the treatment of NPC.

In Singapore, the NDA application was accepted by the Singapore Health Sciences Authority ("HSA") in January 2024. The HSA has also granted priority review designation for the NDA.

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. Four of the company's innovations have already reached the Chinese or international markets, one of which is toripalimab, China's first domestically produced and independently developed anti-PD-1 monoclonal antibody, approved in China and the US. Additionally, more than 30 drugs are currently in clinical development. 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 3,000 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc). For more information, please visit: http://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