Junshi Biosciences Announces Acceptance of the Supplemental New Drug Application for Toripalimab in Combination with Axitinib for the First-line Treatment of Patients with Unresectable or Metastatic Renal Cell Carcinoma

SHANGHAI, China, July 11, 2023 (GLOBE NEWSWIRE) -- 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 for toripalimab, the company's anti-PD-1 monoclonal antibody, in combination with axitinib for the first-line treatment of patients with unresectable or metastatic renal cell carcinoma ("RCC"), has been accepted by the National Medical Products Administration ("NMPA").

Globally, renal carcinoma is the third most common type of malignancy in the urinary system, and RCC accounts for 80%-90% of all cases. According to data published in the Chinese Medical Journal, in 2022, there were approximately 77,000 new cases of renal carcinoma and 46,000 deaths due to this disease in China. Approximately one-third of the renal carcinoma patients had distant metastasis at initial diagnosis, while 20%-50% of the patients with localized tumors developed distant metastases after nephrectomy. According to the risk classification of the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), patients with low, medium and high-risk metastatic RCC who were receiving anti-vascular targeted treatment demonstrated median overall survival ("OS") rates of 35.3, 16.6 and 5.4 months, respectively. Therefore, the need for new treatment options is more urgent for patients with medium and high-risk advanced RCC compared to low-risk patients.

This supplemental new drug application is mainly based on the RENOTORCH study (NCT04394975). As the first pivotal phase 3 study of immunotherapy for patients with advanced RCC in China, RENOTORCH is a multi-center, randomized, open-label, active-controlled study aiming to evaluate the efficacy and safety of toripalimab in combination with axitinib versus sunitinib monotherapy for the first-line treatment of patients with intermediate to high-risk unresectable or metastatic RCC. The study was jointly led by principal investigators Professor Jun GUO of the Peking University Cancer Hospital and Professor Yiran HUANG of Renji Hospital affiliated to Shanghai Jiao Tong University School of Medicine.

According to the study's interim analysis, toripalimab in combination with axitinib for the first-line treatment of patients with advanced RCC significantly reduced the risk of disease progression or death compared to sunitinib monotherapy, while improving secondary endpoints such as ORR. The safety profile of toripalimab in the study was consistent with known risks, and no new safety signals were identified. Further details on the study data will be presented at an upcoming international academic conference.

Dr. Jianjun ZOU, the Global Research and Development President of Junshi Biosciences, expressed her enthusiasm regarding the acceptance of this application. "Currently, China's primary approach towards treating advanced RCC still relies heavily on targeted monotherapy using TKIs, and unfortunately, the benefits from this treatment are minimal for patients. We are therefore immensely excited about the RENOTORCH study, a Chinese-led clinical trial conducted in the Chinese population that has demonstrated that combining toripalimab with axitinib can significantly prolong patients' progression-free survival (PFS). This means that the field of renal cancer treatment in China may soon welcome its very first 'immune-targeting' combination therapy. We will actively communicate and collaborate with

regulatory authorities and hope to soon provide more effective and accessible treatment options to Chinese patients."

About RENOTORCH

The RENOTORCH study is a multicenter, randomized, open-label, active-controlled phase 3 study aiming to evaluate the efficacy and safety of toripalimab in combination with axitinib versus sunitinib monotherapy for the first-line treatment of patients with intermediate to high-risk unresectable or metastatic RCC. Enrolled individuals were randomly assigned in a 1:1 ratio to receive toripalimab in combination with either axitinib or sunitinib until disease progression or intolerable toxicity. The primary endpoint is PFS as assessed by the Independent Radiographic Review Committee ("IRC"), and secondary endpoints include PFS as assessed by investigators, ORR as assessed by IRC or investigators, duration of response (DOR), disease control rate (DCR), OS, safety profile, etc. The study is jointly led by principal investigators Professor Jun GUO of the Peking University Cancer Hospital and Professor Yiran HUANG of Renji Hospital affiliated to Shanghai Jiao Tong University School of Medicine. The study was launched in August 2020, with 47 domestic centers participating and 421 patients enrolled and randomized.

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 six 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).

The first three indications have been included in the National Reimbursement Drug List (NRDL) (2022 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma.

In the United States, the Biologics License Application (BLA) for toripalimab in combination with gemcitabine/cisplatin for the first-line treatment of patients with advanced recurrent or metastatic NPC and toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy is under review by the U.S. Food and Drug Administration ("FDA"). The FDA has granted Breakthrough Therapy designations for toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC as well as for toripalimab monotherapy in the second or third-line treatment of recurrent or metastatic NPC. Additionally, the FDA has granted Fast Track designation for toripalimab for the treatment of mucosal melanoma and 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 United Kingdom's Medicines and Healthcare products Regulatory Agency (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.

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. Junshi Biosciences was the first Chinese pharmaceutical company that obtained marketing approval for an anti-PD-1 monoclonal antibody in China. Its first-in-human anti-BTLA monoclonal antibody for the treatment of various cancers was the first in the world to be approved for clinical trials by the FDA and NMPA and has since entered Phase Ib/II trials in both China and the US. Its anti-PCSK9 monoclonal antibody was the first in China to be approved for clinical trials by the NMPA.

In the face of the pandemic, Junshi Biosciences' response was strong and immediate, joining forces with Chinese and international scientific research institutions and enterprises to develop an arsenal of drug candidates to combat COVID-19, taking the initiative to shoulder the social responsibility of Chinese

pharmaceutical companies by prioritizing and accelerating COVID-19 R&D. In 2021, JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 administered with bamlanivimab, was granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. Meanwhile, VV116 (deuremidevir hydrobromide), a novel oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, has been approved for marketing in China and Uzbekistan. The JS016 and VV116 programs are a part of the company's continuous efforts towards innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has about 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