Junshi Biosciences Announces Primary Endpoint Met in RENOTORCH Study of Toripalimab for 1st-line Treatment of Advanced Renal Cell Carcinoma

SHANGHAI, China, April 27, 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 pre-specified interim analysis of the RENOTORCH study (NCT04394975) has been completed. RENOTORCH is a multi-center, randomized, open-label, active-controlled phase 3 clinical study evaluating toripalimab in combination with axitinib for the first-line treatment of patients with intermediate to high risk, unresectable or distant metastatic renal cell carcinoma ("RCC"). The Independent Data Monitoring Committee (IDMC) has determined that the primary endpoint of progression free survival ("PFS", based on independent radiographic review) has met the pre-defined efficacy boundary. Junshi Biosciences will communicate with regulatory authorities regarding matters related to the supplemental new drug application in the near future.

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. About one-third of the renal cell carcinoma patients had distant metastasis at initial diagnosis, while 20%-50% of the patients with localized tumors developed distant metastasis 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 was 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.

In recent years, PD-(L)1 inhibitors combined with anti-vascular targeted drugs have achieved success in the first-line treatment of advanced RCC in many countries around the world, replacing anti-vascular targeted drug monotherapy as the new standard. Compared to anti-vascular targeted drug monotherapy, the combination of PD-(L)1 monoclonal antibody and anti-vascular targeted drugs has demonstrated significant improvements in patients' PFS, objective response rate ("ORR"), and OS. However, no therapy combining PD-(L)1 therapy with anti-vascular targeted drugs for the first-line treatment of advanced RCC has been approved in China.

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. Based on the interim analysis of the study, 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.

"Thanks to the collective efforts of the investigators, patients, R&D teams and many others, the RENOTORCH study has been a great success," said Dr. Jianjun ZOU, Global Research and Development President of Junshi Biosciences. "This study represents a crucial milestone for our company as an innovative Chinese pharmaceutical company that aims to address the nation's unmet medical needs. We believe that RENOTORCH's positive results will help bridge the gap in renal cancer PD-(L)1 immunotherapy in China, and we will take all the necessary steps to commercialize this achievement and provide new and effective combination immunotherapy options for domestic patients."

About RENOTORCH

The RENOTORCH study is a multi-center, 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) and disease control rate (DCR), OS, safety profile and 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 of Shanghai Jiao Tong University School of Medicine. The study was launched in August 2020, with 47 domestic centers participating and a total of 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 European countries. 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 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 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 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