Junshi Biosciences Announces Acceptance of the Supplemental New Drug Application for Toripalimab as the First-line Treatment of Extensive-stage Small Cell Lung Cancer

SHANGHAI, China, July 19, 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 etoposide plus platinum for the first-line treatment of patients with extensive-stage small cell lung cancer ("ES-SCLC"), has been accepted for review by the National Medical Products Administration ("NMPA").

According to data released by GLOBOCAN 2020, lung cancer is currently the most prevalent malignant tumor with the highest mortality rate in China. Small cell lung cancer ("SCLC") is the most aggressive subtype of lung cancer, accounting for approximately 15%-20% of all lung cancer cases with characteristics including rapid progression, early metastasis and a poor prognosis. SCLC is divided into limited-stage small cell lung cancer ("LS-SCLC") and ES-SCLC. For patients with LS-SCLC, standard chemotherapy and radiotherapy can achieve an objective response rate of approximately 90% and a five-year survival rate of approximately 25%. However, most patients are diagnosed with ES-SCLC by the time they seek medical treatment, with a median survival time of less than one year and a two-year survival rate below 10%. SCLC, and particularly ES-SCLC, pose a significant and unresolved medical challenge.

The supplemental new drug application is mainly based on EXTENTORCH (NCT04012606), a randomized, double-blind, placebo-controlled, multi-center Phase 3 clinical study. EXTENTORCH aims to compare the efficacy and safety of toripalimab or placebo in combination with etoposide plus platinum for the first-line treatment of ES-SCLC. The principal investigator for this study is Professor Ying CHENG, who is from Jilin Cancer Hospital and serves as the vice president of the Chinese Society of Clinical Oncology (CSCO).

EXTENTORCH was launched in 51 centers nationwide, where patients were randomized in a 1:1 ratio to receive either toripalimab or placebo in combination with etoposide plus platinum. The treatment would be administered for 4-6 cycles, after which patients would receive maintenance treatment with toripalimab or placebo until disease progression, intolerable toxicity or other circumstances requiring termination of treatment as specified in the protocol.

In May 2023, the primary endpoints of EXTENTORCH met their pre-defined efficacy boundaries, and toripalimab thus became the first PD-1 inhibitor in the world that met the primary endpoints of both overall survival ("OS") and progression-free survival ("PFS") in a Phase 3 study for the first-line treatment of ES-SCLC.

The results showed that, compared to chemotherapy alone, toripalimab in combination with chemotherapy for the first-line treatment of ES-SCLC could significantly prolong the PFS and OS of patients. The safety profile of toripalimab was similar to previous studies, and no new safety signals were identified. Detailed data will be presented at an upcoming international academic conference.

"SCLC presents with less noticeable early symptoms, and due to its rapid tumor proliferation and high malignancy, many patients are already late-stage or have systemic metastasis at the time of their initial diagnosis," said Professor Ying CHENG of Jilin Cancer Hospital. "For those diagnosed with ES-SCLC, their average survival time is only about a year. However, EXTENTORCH has successfully confirmed that combining toripalimab with chemotherapy as a first-line treatment for ES-SCLC can significantly improve patients' PFS and OS. These results may offer a broader range of more effective treatment options for ES-SCLC patients."

"It was my great pleasure today to witness the successful sNDA submission for toripalimab's 10th indication," said Dr. Jianjun ZOU, the Global Research and Development President of Junshi Biosciences. "Since its clinical approval in late 2015, toripalimab has been addressing the unmet medical needs of patients in China and worldwide. Over 40 registered clinical trials have been conducted to further investigate toripalimab, which has continued to demonstrate stable and powerful anti-tumor activity across various tumor types. In lung cancer alone, toripalimab has been involved in 3 successful large-scale phase 3 clinical trials encompassing diverse subtypes and stages of disease progression. We will work diligently on marketing applications relevant to the indication and strive to help more cancer patients with our innovative therapies!"

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