Junshi Biosciences Announces Acceptance of the Supplemental New Drug Application for Toripalimab as Perioperative Treatment for Operable NSCLC Patients

SHANGHAI, China, April 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, today announced the acceptance of the supplemental new drug application for toripalimab in combination with chemotherapy as perioperative treatment and toripalimab monotherapy as consolidation therapy after adjuvant therapy for the treatment of resectable stage III non-small cell lung cancer ("NSCLC") by the National Medical Products Administration ("NMPA").

"This newly applied indication for operable NSCLC patients will open the door to the clinical application of toripalimab in the early stages of the disease,"said Dr. Jianjun ZOU, President of Global Research and Development at Junshi Biosciences. "The Neotorch study has created a new model of perioperative immunotherapy for NSCLC in China, enabling the use of immunotherapy throughout the preoperative, postoperative, and consolidation maintenance processes. We will work closely with regulatory authorities to ensure Chinese patients can benefit from this innovative therapy first and enhance the curative prospects for those with NSCLC."

Lung cancer is currently the second most prevalent type of cancer with the highest mortality rate in the world. According to data released by the World Health Organization, in 2020, the number of new lung cancer cases in China reached 816,000 and accounted for 17.9% of all new cancer cases in China. In the same year, the number of lung cancer deaths in China reached 715,000 and accounted for 23.8% of all cancer deaths in China. NSCLC is a major subtype of lung cancer, accounting for approximately 85% of all cases. Among these patients, 20%-25% are eligible for surgical resection at first diagnosis, but even after radical surgical treatment, 30%-55% of these patients experience post-surgical recurrence and death. While radical surgery in combination with chemotherapy can prevent recurrence, chemotherapy as preoperative neoadjuvant or postoperative adjuvant therapy has limited clinical benefit, raising the 5-year survival rate of patients by only about 5%.

This supplemental new drug application is based on the Neotorch study (NCT04158440), a randomized, double-blind, placebo-controlled, multi-center phase III clinical study led by Professor Shun LU of Shanghai Chest Hospital as the principal investigator. The study was conducted in 56 centers nationwide. Patients with operable NSCLC received toripalimab/placebo in combination with platinum-containing doublet chemotherapy as neoadjuvant and adjuvant therapy, and received toripalimab/placebo monotherapy as consolidation therapy after postoperative adjuvant therapy. The type of platinum-containing doublet chemotherapy was selected by investigators according to

treatment practices of therapeutic institutions—paclitaxel in combination with cisplatin was given to patients with squamous NSCLC, while pemetrexed in combination with cisplatin was given to patients with non-squamous NSCLC.

In January 2023, an interim analysis by the Independent Data Monitoring Committee (IDMC) determined that the primary endpoint of the Neotorch study, event-free survival ("EFS"), had met the pre-defined efficacy boundary. Neotorch is the world's first phase III registered study demonstrating that perioperative treatment with anti-PD-1 monoclonal antibody significantly extends EFS of patients with operable NSCLC. Results of the interim analysis showed that, compared with chemotherapy alone, toripalimab in combination with chemotherapy as perioperative treatment for stage III operable NSCLC patients and toripalimab monotherapy for consolidation therapy thereafter could significantly extend EFS of patients.

The comprehensive data will be disclosed internationally for the first time in an oral presentation at the ASCO Plenary Series on April 20, 2023, at 3 p.m. (U.S. Eastern time).

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").
7. 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.

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