Junshi Biosciences Announces Toripalimab plus Chemotherapy Significantly Improved Event-free Survival (EFS) versus Chemotherapy as Perioperative Treatment for Resectable Stage III Non-small Cell Lung Cancer (NSCLC) in Phase 3 Neotorch Study

- Perioperative toripalimab plus chemotherapy significantly improved EFS and reduced risk of disease recurrence, progression events or death by 60% among resectable stage III NSCLC patients, compared to chemotherapy alone
- Results from the Neotorch study were presented during the ASCO April Plenary Series

SHANGHAI, China, April 21, 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 that positive interim event-free survival (EFS) results from the Neotorch study were presented at the ASCO April Plenary Series.

Neotorch is the world's first phase 3 registered study demonstrating that perioperative treatment with anti-PD-1 monoclonal antibody significantly extends EFS of patients with resectable non-small cell lung cancer (NSCLC). It aims to evaluate the efficacy and safety of perioperative toripalimab, Junshi Biosciences' anti-PD-1 monoclonal antibody, in combination with chemotherapy, followed by toripalimab maintenance versus perioperative chemotherapy alone in resectable stage II/III NSCLC.

Among 404 stage lll NSCLC patients, the interim EFS analysis after a median follow-up of 18.25 months (cut-off date: Nov 30, 2022) revealed a significant EFS improvement in the toripalimab arm (HR = 0.40 [95% Cl, 0.277-0.565]; two-sided P < 0.0001). The median EFS was not reached in the toripalimab arm while it was 15.1 months in the placebo arm. Toripalimab demonstrated a consistent favorable effect on EFS in all subgroups, regardless of PD-L1 expression status.

In the toripalimab arm, the major pathological response (MPR) and pathologic complete response (pCR) rates per blinded independent pathologic review (BIPR) of the study were also higher compared to the placebo arm, with rates of 48.5% vs. 8.4% (P<0.0001) and 24.8% vs. 1.0% (P<0.0001), respectively.

Similarly, the overall survival (OS) results showed a trend favoring toripalimab. The median OS was not reached in the toripalimab arm, while it was 30.4 months in the placebo arm (HR=0.62). OS will be formally tested at the final analysis.

In addition, after neoadjuvant therapy, more patients from the toripalimab arm underwent surgery compared to the placebo arm (82.2% vs. 73.3%), 95.8% and 92.6% of the patients underwent surgery

and achieved R0 resection, respectively. The treatment was well-tolerated, with no new safety signals identified.

Based on the Neotorch study, the National Medical Products Administration of China (NMPA) has accepted the supplemental new drug application (sNDA) for toripalimab in combination with chemotherapy as perioperative treatment and toripalimab monotherapy as maintenance therapy after adjuvant therapy for the treatment of resectable stage III NSCLC.

“The Neotorch study has pioneered the world’s first ‘3+1+13’ perioperative treatment model for NSCLC, which incorporates immunotherapy into both preoperative neoadjuvant and postoperative adjuvant treatments,” said Neotorch’s Principal Investigator, Professor Shun LU from the Shanghai Chest Hospital. “The study results show that the addition of toripalimab to chemotherapy provided a superior EFS in stage III NSCLC patients than chemotherapy alone, while maintaining a manageable safety profile. We are hopeful that our innovative solution will further improve the effectiveness and assessibility of lung cancer treatments and medications and ignite a new torch of hope for patients!”

Dr. Jianjun ZOU, President of Global Research and Development at Junshi Biosciences, “Lung cancer has the highest mortality rate of all malignant cancers worldwide. Even with radical surgery in the earlier stages, some patients still experience recurrence or death. Today, immunotherapy has become standard of care for various late-stage cancers, and the exploration of its potential use as early-stage treatment is showing promising results. The Neotorch study has strengthened our resolve to find a cure for more cancer patients. The NMPA is currently reviewing our sNDA for the new indication based on the Neotorch data, and we are excited to work together to benefit early-stage lung cancer patients with this innovative therapy!”

About the Neotorch Study

The Neotorch Study (NCT04158440) is a randomized, double-blind, placebo-controlled, Phase III trial evaluating the efficacy and safety of perioperative toripalimab plus chemotherapy, followed by toripalimab maintenance versus chemotherapy in resectable stage II/III NSCLC. Patients with stage II/III resectable NSCLC and without EGFR/ALK alterations for non-squamous NSCLC were randomized 1:1 to receive 240 mg toripalimab or placebo, combined with chemotherapy Q3W for 3 cycles before surgery and one cycle after surgery, followed by toripalimab or placebo monotherapy Q3W for 13 cycles. The chemotherapy backbones varied depending on the histology of the cancer, with paclitaxel or docetaxel plus platinum for squamous cell carcinoma, and pemetrexed plus platinum for non-squamous cell carcinoma. Stratification variables for randomization included disease stage, histopathologic subtype, PD-L1 expression and surgical procedure. Primary endpoints were EFS as assessed by investigator and MPR rate as assessed by BIPR in the stage III and the ITT populations.

Secondary endpoints included OS, pCR rate, EFS as assessed by independent review committee (IRC), and safety.

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.

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