Junshi Biosciences Announces Toripalimab as Perioperative Treatment for Operable NSCLC Patients Met Primary Endpoint in Phase 3 Clinical Study

SHANGHAI, China, January 17, 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 today that a randomized, double-blind, placebo-controlled, multi-center phase III clinical study ("Neotorch", NCT04158440) of the company's anti-PD-1 monoclonal antibody, toripalimab, in combination with platinum-containing doublet chemotherapy as perioperative treatment for operable non-small cell lung cancer ("NSCLC") patients, has finished the pre-specified interim analysis. The Independent Data Monitoring Committee (IDMC) has determined that the primary endpoint of event-free survival ("EFS") 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.

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 amounted to 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 amounted to 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. Amongst these patients, 20%-25% are surgically resectable at first diagnosis, but even after radical surgical treatment, 30%-55% of such patients will suffer from post-surgical recurrence and death. Radical surgery in combination with chemotherapy is a way to prevent recurrence, but chemotherapy, as preoperative neoadjuvant or postoperative adjuvant therapy, has limited clinical benefit and can only raise the 5-year survival rate of patients by approximately 5%.

Immuno-oncology (I-O) therapy, a type of treatment best represented by PD-(L)1 inhibitors, can provide patients with long-term tumor control or elimination. By relieving the immune suppression of immune cells caused by cancer cells, PD-(L)1 inihibitors reactivate the patients' own immune system to destroy cancer. At present, the global community has accumulated sufficient clinical evidence proving that I-O can significantly improve the overall survival of patients with advanced NSCLC. However, the research on patients with operable NSCLC began relatively recently and focused solely on preoperative neoadjuvant or postoperative adjuvant I-O therapy. Perioperative I-O therapy covering the whole process, including pre- and post-surgery, is expected to be a better treatment model for patients.

Neotorch is the world's first phase III registered study of perioperative I-O therapy for lung cancer with a positive EFS result. Led by Professor Shun LU of Shanghai Chest Hospital as primary researcher, the study is a randomized, double-blind, placebo-controlled, multicenter phase III clinical study aiming to compare the efficacy and safety of toripalimab in combination with platinum-containing doublet chemotherapy versus placebo in combination with platinum-containing doublet chemotherapy for

patients with operable NSCLC. The primary endpoints are EFS as assessed by researchers and major pathological remission rate ("MPR rate") as assessed by the Blind Independent Pathology Review Committee ("BIPR"). The secondary endpoints include pathological complete remission rate (pCR rate) as assessed by BIPR and researchers, EFS as assessed by Independent Review Committee ("IRC"), and disease free survival (DFS), overall survival (OS) and safety as assessed by IRC and researchers, etc.

The study was launched 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 monotherapy as consolidation therapy after postoperative adjuvant therapy. Platinum-containing doublet chemotherapy was selected by researchers according to treatment practices of therapeutic institutions, of which paclitaxel in combination with cisplatin was for patients with squamous NSCLC, while pemetrexed in combination with cisplatin was for non-squamous NSCLC.

Based on the interim analysis, compared with chemotherapy alone, toripalimab in combination with chemotherapy as perioperative treatment for phase III operable NSCLC patients and toripalimab monotherapy for consolidation therapy thereafter may significantly extend EFS of patients.
The safety data of toripalimab is in line with known risks, with no new safety signals identified.

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 thirty 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 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) (2021 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for treatment of melanoma and NPC.

In the United States, the Food and Drug Administration (FDA) is reviewing the Biologics License Application (BLA) resubmission for toripalimab in combination with gemcitabine and cisplatin as first-line treatment for patients with advanced recurrent or metastatic NPC and for toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy. 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 submitted to the European Medicines Agency (EMA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) in November 2022 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, the EMA accepted the MAA.

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. Among the many drug candidates is JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 and the result of the combined efforts of Junshi Biosciences, the Institute of Microbiology of the Chinese Academy of Science and Lilly. JS016 administered with bamlanivimab has been granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. As of December 3 2021, over 700,000 patients have been treated with bamlanivimab or bamlanivimab and etesevimab, potentially preventing more than 35,000 hospitalizations and at least 14,000 deaths. Meanwhile, VV116, a new oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, is in global Phase III clinical trials. The JS016 and VV116 programs are a part of the company's continuous innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has more than 3,100 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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