Junshi Biosciences Receives NMPA Approval of sNDA for Toripalimab in Combination with Paclitaxel and Cisplatin in First-Line Treatment of Advanced or Distant Metastatic Esophageal Squamous Cell Carcinoma

--5th approved indication by NMPA significantly expands eligible patient population

SHANGHAI, China, May 16, 2022 (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 the China National Medical Products Administration (NMPA) has approved the supplemental new drug application (sNDA) for toripalimab in combination with paclitaxel and cisplatin in the first-line treatment of patients with unresectable locally advanced/recurrent or distant metastatic esophageal squamous cell carcinoma (ESCC). The sNDA was accepted by the NMPA in July 2021. This is the fifth indication approved for toripalimab in China and will benefit Chinese patients with advanced ESCC.

The approval of the sNDA is based on results from the JUPITER-06 study (NCT03829969), a randomized, double-blind, placebo-controlled, multi-center Phase III clinical study. JUPITER-06 compared the efficacy and safety of toripalimab in combination with TP chemotherapy (paclitaxel + cisplatin) and placebo in combination with TP chemotherapy in the first-line treatment of patients with advanced or metastatic ESCC. The study results showed that, compared with chemotherapy alone, toripalimab in combination with TP chemotherapy demonstrated a statistically significant increase in survival benefits, with median overall survival (mOS) significantly extended to 17 months, progression-free survival (PFS) to 5.7 months, disease progression or mortality risk reduced by 42% (HR=0.58, P<0.0001), and patients benefiting regardless of their PD-L1 expression. In terms of safety, no new safety signal was found when adding toripalimab to the chemotherapy treatment. The results of JUPITER-06 were published in Cancer Cell.

"China is one of the countries with the highest incidence of esophageal cancer," said Professor Ruihua Xu from Sun Yat-sen University Cancer Center, the principal investigator of JUPITER-06. "However, due to the differences between Eastern and Western patients in terms of cause of the disease and pathological characteristics, clinical evidence for innovative treatments specifically targeting the main subtypes of ESCC in China is relatively lacking. JUPITER-06 has demonstrated that a PD-1 inhibitor independently developed in China, combined with a TP chemotherapy regime, is more suitable for Chinese clinical practice. The results, to our surprise, were overwhelmingly positive. PFS and OS improved so significantly that patients broke the record in the survival of advanced ESCC in first-line treatment. This 'China Protocol' is a major contribution to the international field of immunotherapy."

"The symptoms of early esophageal cancer patients are insidious and difficult to be detected. Many patients are already at advanced stages when they are diagnosed initially. However, chemotherapy, the

standard first-line treatment for advanced ESCC, has a poor prognosis," said Dr. Jianjun Zou, Global Research and Development President at Junshi Biosciences. "Through our combined efforts with JUPITER-06 investigators and participating patients, the study confirmed that toripalimab combined with chemotherapy significantly increases treatment efficacy. We look forward to bringing the better treatment option to these patients in China and will also actively communicate with regulatory agencies in other countries to make this innovative therapy beneficial to patients all over the world."

"We are excited that the approval of the new indication of first-line treatment of advanced ESCC for toripalimab allows us to bring our immuno-oncology therapy to more patients, including those with low PD-L1 expressing tumors for whom available checkpoint inhibitors appear to be less effective," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "We will continue to focus on exploring the potential of I-O drugs in treating tumors with unmet medical needs."

About Esophageal Cancer

Esophageal cancer is one of the most common malignant tumors in alimentary tract. According to data released by GLOBOCAN 2020, in 2020, 320,000 new esophageal cancer cases and 300,000 deaths due to esophageal cancer occurred in China, both accounting for more than half of the global total. The incidence and death rates of esophageal cancer ranked fifth and fourth among all domestic malignant tumors respectively. ESCC and esophageal adenocarcinoma are the two main histological subtypes of esophageal cancer. ESCC is the main subtype in China, accounting for approximately 90% of all esophageal cancer cases. For patients with advanced ESCC, the current standard first-line treatment is often the platinum-based chemotherapy, but the clinical benefit is limited, and the 5-year overall survival rate remains less than 20%. Therefore, there is an urgent unmet need for new drugs and treatments to extend the survival of patients.

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 five 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 as the first-line treatment of patients with unresectable locally advanced/recurrent or distant metastatic ESCC.

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 melanoma and NPC.

In addition, a sNDA Application for toripalimab is currently under review by the NMPA in China:

- in combination with chemotherapy as the first-line treatment of patients with advanced or metastatic NSCLC without EGFR or ALK mutations.

In the United States, the FDA granted Breakthrough Therapy designation 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. Junshi Biosciences and Coherus plan to resubmit a Biologics License Application (BLA) for toripalimab for advanced NPC by mid-summer 2022. Additionally, the FDA has granted Fast Track designation for toripalimab for the treatment of mucosal melanoma and Orphan Drug Designation for the treatment of esophageal cancer, NPC, mucosal melanoma, soft tissue sarcoma, and SCLC. In 2021, Coherus in-licensed rights to develop and commercialize toripalimab in the United States and Canada. Junshi Biosciences and Coherus plan to file additional toripalimab BLAs with the FDA over the next several years for multiple other cancer types.

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 tumors 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. 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 2,800 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing and Guangzhou). For more information, please visit: http://junshipharma.com.

Junshi Biosciences Contact Information

IR Team:
Junshi Biosciences
info@junshipharma.com
+ 86 021-2250 0300

Goby Global
Bob Ai
bai@gobyglobal.com
+ 1 646-389-6658

PR Team:
Junshi Biosciences
Zhi Li
zhi_li@junshipharma.com
+ 86 021-6105 8800