Toripalimab Plus Chemotherapy as First-Line Treatment for Advanced Esophageal Cancer Reached Primary Endpoints in Phase III Clinical Study

SHANGHAI, China, April 22, 2021 -- 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 Independent Data Monitoring Committee (IDMC) has determined that toripalimab in combination with paclitaxel/cisplatin as the first-line treatment for patients with advanced esophageal squamous cell carcinoma (ESCC) has reached its pre-specified primary endpoints of Progression Free Survival (PFS) and Overall Survival (OS) at the interim analysis of the randomized, double-blind, placebo-controlled, multi-center, phase III clinical study "JUPITER-06" (Clinicaltrials.gov identifier: NCT03829969). Junshi Biosciences will communicate with the regulatory authorities regarding the supplemental New Drug Application (sNDA) in the near future.

About Esophageal Squamouse Cell Carcinoma (ESCC)

Esophageal cancer is a primary malignant tumor of the esophageal mucosa epithelium, which is one of the most common cancers in the world. According to data released by GLOBOCAN 2020, esophageal cancer is the seventh most common malignant tumor in the world and the sixth leading cause of cancer death. In 2020, approximately 320,000 new esophageal cancer cases and approximately 300,000 deaths due to esophageal cancer occurred in China, with the incidence and death rates ranking fifth and fourth among all malignant tumors, respectively. Esophageal squamous cell carcinoma and adenocarcinoma are the two main histological subtypes of esophageal cancer. Esophageal squamous cell carcinoma is the main subtype in China, accounting for 90% of all esophageal cancer. For patients with advanced esophageal squamous cell carcinoma, the current standard first-line treatment is platinum based chemotherapy, but the 5-year overall survival rate is less than 20%.

About JUPITER-06 Study

The JUPITER-06 study was a randomized, double-blind, placebo-controlled, multicenter phase III trial that aimed to compare the efficacy and safety of toripalimab combined with paclitaxel/cisplatin versus placebo combined with paclitaxel/cisplatin as first-line treatments for advanced esophageal squamous cell carcinoma. Professor Ruihua Xu from the Sun Yat-sen University Cancer Hospital is the principal investigator of the JUPITER-06 study. A total of 514 patients were enrolled in the study. The primary endpoints were progression-free survival (PFS) as assessed by the Blinded Independent Review Committee (BICR) and overall survival (OS). Secondary endpoints included the PFS assessed by investigator, objective response rate (ORR), disease control rate (DCR) and duration of response (DOR).

Based on the results of interim analysis, the Independent Data Monitoring Committee (IDMC) determined that both primary endpoints of PFS and OS have crossed the prespecified efficacy boundaries and the results show that compared with the paclitaxel/cisplatin chemotherapy , toripalimab combined with paclitaxel/cisplatin significantly prolonged the PFS and OS of patients with advanced esophageal squamous carcinoma.

About Toripalimab

Toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing in China. More than thirty company-sponsored clinical studies covering more than fifteen indications have been conducted globally, including in China and the United States. On 17 December 2018, toripalimab was granted a conditional approval from the National Medical Products Administration (NMPA) for the second-line treatment of unresectable or metastatic melanoma. In December 2020, toripalimab was successfully included in the updated National Reimbursement Drug List. In February 2021, the supplemental NDA for toripalimab for the treatment of patients with recurrent or metastatic nasopharyngeal carcinoma after failure of at least two lines of prior systemic therapy was granted a conditional approval by the NMPA. In April 2021, the supplemental NDA for toripalimab for the treatment of patients with locally advanced or metastatic urothelial carcinoma who failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-

containing chemotherapy was granted a conditional approval.

In February 2021, the supplemental NDA application of toripalimab in combination with chemotherapy for the first-line treatment of patients with advanced, recurrent or metastatic nasopharyngeal carcinoma was accepted by the NMPA. In March 2021, toripalimab was included in the Drug List of the Procedure for Breakthrough Therapy Designation for the first-line treatment of advanced mucosal melanoma by the National Medical Products Administration. In the same month, Junshi Biosciences submitted the Biologics License Application of toripalimab for the treatment of recurrent or metastatic nasopharyngeal carcinoma to the US Food and Drug Administration (FDA). As of the date of this announcement, toripalimab has been granted 1 Breakthrough, 1 Fast Track and 3 Orphan Drug Designations (ODD) by the FDA for the treatment of mucosal melanoma, nasopharyngeal carcinoma, and soft tissue sarcoma.

About Junshi Biosciences

Founded in December 2012, Junshi Biosciences 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 28 innovative drug candidates and 2 biosimilars, 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 antibody for solid tumors was the first in the world to be approved for clinical trials by the FDA and NMPA and its anti-PCSK9 monoclonal antibody was the first in China to be approved for clinical trials by the NMPA. In early 2020, Junshi Biosciences joined forces with the Institute of Microbiology Chinese Academy of Science and Eli Lilly to co-develop JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2. JS016 administered with bamlanivimab has received Emergency Use Authorization (EUA) from the US FDA in February 2021 for the treatment of recently diagnosed, mild to moderate COVID-19 in patients who are at a high risk of progressing to severe COVID-19 and/or hospitalization. The JS016 program is a part of our continuous innovation for disease control and prevention of the global pandemic. Junshi Biosciences has over 2,000 employees in the United States (San Francisco and Maryland) and China (Shanghai,

Suzhou, Beijing and Guangzhou). For more information, please visit: http://junshipharma.com.