Junshi Biosciences Announces Acceptance by the NMPA of Supplemental New Drug Application for Toripalimab Combined with Chemotherapy for The First-Line Treatment of Nasopharyngeal Carcinoma

- *The 3rd sNDA for Toripalimab in China*

SHANGHAI, China, Feb. 19, 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 National Medical Products Administration (NMPA) of China has accepted its supplemental New Drug Application (sNDA) for Toripalimab combined with chemotherapy for the first-line treatment of patients with recurrent or metastatic nasopharyngeal carcinoma.

The supplemental NDA is based on the JUPITER-02 study (NCT03581786), which is a randomized, double-blind, placebo-controlled Phase III study led by Professor Ruihua Xu from Sun Yat-sen University Cancer Center. The results of the study showed that Toripalimab combined with gemcitabine/cisplatin as a first-line treatment for patients with recurrent or metastatic nasopharyngeal carcinoma significantly prolonged the progression-free survival as compared with the standard first-line treatment of gemcitabine/cisplatin. This study is the world's largest international Phase III clinical study for any checkpoint inhibitor combined with chemotherapy in the first-line treatment of recurrent or metastatic nasopharyngeal carcinoma.

Junshi Biosciences has developed clinical programs using Toripalimab alone or in combination with other therapies for the treatment of nasopharyngeal carcinoma regardless of extent of prior treatments. The company has submitted two sNDAs of toripalimab for the treatment of NPC in China. Toripalimab also obtained Breakthrough Therapy and Orphan Drug Designations from the US FDA for this indication, and its Biologics License Applications (BLA) in the United States will be submitted in the near future. Toripalimab is likely to become the first Chinese anti-PD-1 monoclonal antibody to achieve commercialization in the overseas markets.

About Nasopharyngeal carcinoma

Nasopharyngeal carcinoma is a malignant tumor that occurs in nasopharyngeal mucosal epithelium, which is one of the most common head and neck cancers. According to the World Health Organization, the number of newly diagnosed nasopharyngeal carcinoma cases in 2020 has reached approximately 133,000 worldwide, and nearly half of the cases occurred in China.

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 obtained a conditional approval from the NMPA for the second-line treatment of unresectable or metastatic melanoma. Toripalimab was included in the 2019 and 2020 Guidelines of Chinese Society of Clinical Oncology (CSCO) for the Diagnosis and Treatment of Melanoma. Two supplemental New Drug Applications ("NDAs") of Toripalimab for the third-line treatment of recurrent or metastatic nasopharyngeal carcinoma and the second-line treatment of metastatic urothelial carcinoma were accepted by the NMPA in April 2020 and May 2020, respectively. Both supplemental NDAs received priority review designations from the NMPA in July 2020. In addition, Toripalimab has been granted Breakthrough Therapy Designation ("BTD") by the US Food and Drug Administration ("FDA") for the treatment of recurrent or metastatic nasopharyngeal carcinoma in

September 2020. In December 2020, Toripalimab Injection was successfully included in the updated National Reimbursement Drug List ("NRDL"). Currently, Toripalimab has been granted 1 Breakthrough, 1 Fast Track , and 3 Orphan Drug Designations by the FDA for the treatment of mucosal melanoma, nasopharyngeal carcinoma, and soft tissue sarcoma.

About Junshi Biosciences

Founded in December 2012, Junshi Biosciences (HK: 1877; SH: 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 27 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, China's first neutralizing fully human monoclonal antibody against SARS-CoV-2, which has entered clinical trials and is now 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**.