NMPA Approves Toripalimab in Patients with Recurrent or Metastatic Nasopharyngeal Carcinoma after Failure of at Least Two Lines of Prior Systemic Therapy

- *1st approval of any checkpoint inhibitor in nasopharyngeal carcinoma in the world*
- *2nd indication approved for Toripalimab in China*

SHANGHAI, China, Feb. 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 National Medical Products Administration (NMPA) of China has granted a conditional approval to toripalimab for the treatment of patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) after failure of at least two lines of prior systemic therapy. This is the first approval of immune checkpoint blockade therapy in NPC in the world and the second approved indication for toripalimab in China. In December 2018, Toripalimab obtained a conditional approval from the NMPA for the second-line treatment of unresectable or metastatic melanoma.

In April 2020, the supplemental NDA for Toripalimab in patients with recurrent or metastatic NPC after failure of at least two lines of prior systemic therapy was accepted by the NMPA and received priority review designation from the NMPA in July 2020. The supplemental NDA is based on the POLARIS-02 study (NCT02915432), which is a multi-center, open-label, Phase II pivotal registrational clinical study led by Professor Ruihua Xu from Sun Yat-sen University Cancer Center. The study enrolled a total of 190 patients with recurrent or metastatic NPC after failure of prior systemic therapy. The POLARIS-02 study is the world's largest clinical study for any immune checkpoint inhibitor monotherapy for the treatment of recurrent or metastatic NPC. In January 2021, the results of the POLARIS-02 study were published online in the Journal of Clinical Oncology.

The results of the POLARIS-02 study showed that Toripalimab demonstrated durable anti-tumor activity and survival benefits regardless of PD-L1 expression status with a manageable safety profile. In 92 patients with recurrent/metastatic NPC after failure of at least two lines of prior systemic chemotherapy, the objective response rate (ORR) was 23.9%; the median duration of response (mDOR) 14.9 months; and the median overall survival (mOS) 15.1 months.

"The great variability in prevalence of NPC across the globe is evident, which leads to challenges in new drug research and development on a global scale. Despite this, unmet medical needs for NPC remain globally. Our data show that NPC is clearly responsive to immunotherapy. It is notable that toripalimab lacks the usual side effects of cytotoxic therapy and is generally well tolerated by patients, showing a great potential for further development in the treatment of NPC," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "As an innovation-driven pharma who follows the 'In China, For Global' strategy, we focus on tumor types that are 1) highly prevalent in China; 2) responsive to immunotherapy; and 3) where there is urgent unmet need for better and safer treatments. We sincerely appreciate the contributions made by investigators and patients of the POLARIS-02 study, empowering us to obtain this critical medical evidence to advance

treatment options for so many. In addition, we have also developed a R & D program for treatment of NPC, regardless of extent of prior treatment, and look forward to providing better treatment options for patients with advanced nasopharyngeal carcinoma in China and beyond."

About Nasopharyngeal carcinoma

Nasopharyngeal carcinoma is a malignant tumor that occurs in the nasopharyngeal mucosal epithelium and is one of the most common head and neck cancers. According to the World Health Organization (WHO), 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. The supplemental NDA of Toripalimab for the second-line treatment of metastatic urothelial carcinoma was accepted by the NMPA in May 2020 and received priority review designations from the NMPA in July 2020. In September 2020, Toripalimab was granted Breakthrough Therapy Designation by the US Food and Drug Administration ("FDA") for the treatment of recurrent/metastatic nasopharyngeal carcinoma. In December 2020, Toripalimab was successfully included in the updated National Reimbursement Drug List. 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. 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 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2. JS016 adminstered with bamlanivimab has received Emergency Use Authorization (EUA) by US FDA in Feb 2021 for the treatment of mild to moderate COVID-19 in patients aged 12 and older who are at high risk for progressing to severe COVID-19 and/or hospitalization. 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**.