**Junshi Biosciences Announces Approval of Supplemental New Drug Application by NMPA for Toripalimab in Combination with Cisplatin and Gemcitabine as First-Line Treatment for Patients with Locally Recurrent or Metastatic Nasopharyngeal Carcinoma**

**--4th approved indication for toripalimab**

SHANGHAI, China, November 29, 2021 -- Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", HKEX: 1877; SSE: 688180) announced today that the National Medical Products Administration (NMPA) of China has approved its supplemental New Drug Application (sNDA) for toripalimab in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic nasopharyngeal carcinoma (the "NPC"). This is the fourth approved indication for toripalimab in China. In December 2018, the NMPA granted a conditional approval to toripalimab for the second-line treatment of unresectable or metastatic melanoma. In February 2021, the NMPA 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. In April 2021, the NMPA granted a conditional approval to 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.

The sNDA is based on the JUPITER-02 study (NCT03581786), which is a randomized, double-blind, placebo-controlled and international multi-center Phase III clinical study led by Professor Ruihua Xu from Sun Yat-sen University Cancer Center. The results of the study showed that when compared with the standard first-line treatment of gemcitabine/cisplatin, toripalimab in combination with gemcitabine and cisplatin as the first-line treatment for patients with recurrent or metastatic NPC has better progression-free survival, higher objective response rate, longer duration of response and survival benefits regardless of PD-L1 expression status with a manageable safety profile. This study is the world's largest Phase III clinical study for a checkpoint inhibitor in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC. The study results of JUPITER-02 were presented in the form of a Late-breaking Abstract (LBA) at the plenary session at the annual meeting of the American Society of Clinical Oncology (ASCO 2021) and were published as the cover article of the September 2021 issue of *Nature Medicine*.

"As the world's first immuno-oncology (I-O) drug approved for the treatment of nasopharyngeal cancer (NPC), we continue to explore the potential of toripalimab in different settings within NPC and across other cancer types, with the support of patients, investigators and our research team participating in clinical trials. We have now received approval for a new indication for toripalimab with chemotherapy for the first-line treatment of NPC, which provides better treatment outcomes for more patients with advanced NPC," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "Junshi Biosciences

focuses 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. The results of POLARIS-02 and JUPITER-02 studies for NPC are representative examples of our clinical program. We are delighted to see that the breakthrough results obtained with toripalimab not only bring new hope to Chinese patients, but also earn international recognition from academia and regulatory authorities. We hope that our novel I-O drug will be available to benefit patients outside China in the near future. "

**About Nasopharyngeal Carcinoma**

NPC is a primary malignant tumor of the 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 NPC cases in 2020 exceeded 130,000 worldwide, and nearly half of the cases occurred in China. The current therapies are limited for recurrent or metastatic NPC. The first-line standard therapy is platinum-based dual-drug combination chemotherapy. The overall survival of the patients is poor.

**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 is thought to recharge 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, 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®). On December 17, 2018, toripalimab was granted a conditional approval by 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 NMPA 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. In April, the NMPA granted a conditional approval to 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. In November 2021, the NMPA approved toripalimab in combination with cisplatin and gemcitabine as the first-line treatment for patients with

locally recurrent or metastatic nasopharyngeal carcinoma. In addition, the supplemental NDA for the first-line treatment of patients with advanced or metastatic esophageal squamous cell carcinoma was accepted by the NMPA for review in July 2021.

In the United States, the FDA has granted priority review for the toripalimab BLA for the treatment of recurrent or metastatic NPC, an aggressive head and neck tumor which currently has no FDA-approved immuno-oncology treatment options. Earlier, the FDA granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the 1st 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 designation for esophageal cancer, NPC, mucosal melanoma and soft tissue sarcoma. Earlier in 2021, Coherus in-licensed rights to develop and commercialize toripalimab in the United States and Canada. Coherus and Junshi Biosciences plan to file additional toripalimab BLAs with the FDA over the next three 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 45 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 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 of 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 been granted Emergency Use Authorizations (EUA) in 15 countries and regions worldwide. The JS016 program is a part of our continuous innovation for disease control and prevention of the global pandemic. Junshi Biosciences has over 2,500 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing and Guangzhou). For more information, please visit: http://junshipharma.com.