NMPA Approves Toripalimab in 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

3rd indication approved for Toripalimab in China

SHANGHAI, China, April 12, 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 locally advanced or metastatic urothelial carcinoma who failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. This is the third 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.

"Following the approval of indications in melanoma and nasopharyngeal carcinoma, toripalimab has reached a new milestone in the treatment of urothelial carcinoma, under the joint efforts of patients, investigators, and our R&D personnel," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "Junshi Biosciences has pioneered clinical exploration for unselected UC patients in China and achieved remarkable results, which makes us very excited and confident in the development potential of toripalimab as an anti-tumor drug with a broad therapeutic profile. We also look forward to providing Chinese UC patients with more treatment options that work better and cost less through the company's collaboration with AstraZeneca."

The supplemental NDA is based on the POLARIS-03 study (NCT03113266) led jointly by Professor Guo Jun of the Peking University Cancer Hospital and Professor Huang Yiran of Renji Hospital affiliated to the Shanghai Jiao Tong University School of Medicine. Among the 136 patients with locally advanced or metastatic urothelial carcinoma after failure of platinum-based chemotherapy including neoadjuvant or adjuvant chemotherapy within 12 months, the evaluation results of the Independent Review Committee (IRC) indicated that the overall objective response rate (ORR) was 27.2%, the disease control rate (DCR) was 46.3% and the median overall survival (mOS) reached 14.6 months. The median duration of response (DOR) had not yet reached a mature stage, with 67.1% of patients with objective responses continuing after a 12-month period.

POLARIS-03 is the first pivotal clinical study on the treatment of advanced urothelial carcinoma with an unselected population after failure of first-line standard treatment in China. Data showed that toripalimab demonstrated explicit anti-tumor activity and continuous efficacy among all patients and within each subgroup. ORR of all patients was 27.2%. ORR of PD-L1 positive patients reached 42.2%. ORR of PD-L1 negative patients reached 18.8%. Therefore, advanced urothelial carcinoma patients benefit from toripalimab regardless of PD-L1 expression. In addition, the safety and tolerability of toripalimab were consistent with previous research results.

About Urothelial Carcinoma

Urothelial carcinoma (UC) is the most common (more than 90%) histologic type of bladder cancer in China. It is one of the ten most common cancer types in the country. UC easily metastasizes and patients often relapse. With a lack of treatment options, UC has become a major health concern in China and severely affects the lives of patients. While earlier stages of UC can be treated through surgery, for patients with unresectable or metastatic UC, platinum-based chemotherapy is the current standard of care. Unfortunately, patients often become resistant to platinum-based chemotherapy and relapse.

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 December 17, 2018, Toripalimab obtained a conditional approval from the National Medical Products Administration (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 designation 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 or metastatic nasopharyngeal carcinoma. In December 2020, Toripalimab was successfully included in the updated National Reimbursement Drug List. In February 2021, the supplemental NDA for 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 the same month, 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. 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 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.

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