Junshi Biosciences Announces NMPA Acceptance of New Drug Applications for Toripalimab Injection (Subcutaneous) Across 12 Indications

SHANGHAI, China, March 9, 2026 -- Shanghai Junshi Biosciences Co., Ltd (Junshi Biosciences, HKEX: 1877; SSE: 688180), a leading innovation-driven biopharmaceutical company dedicated to the discovery, development, and commercialization of novel therapies, announced that the new drug applications (the "NDAs") for the company's product, toripalimab injection (subcutaneous injection [code: JS001sc]), for 12 indications in the treatment of tumors has been accepted by the National Medical Products Administration ("NMPA"). JS001sc is the first domestic anti-PD-1 monoclonal antibody in a subcutaneous formulation to enter the marketing application stage.

According to data released by GLOBOCAN 2022, in 2022, there were 4.8247 million new cancer cases and 2.5742 million cancer-related deaths in China. Immunotherapy (I-O), represented by anti-PD-1 monoclonal antibodies, has become a cornerstone treatment for various malignant tumors, including lung cancer, breast cancer, liver cancer, esophageal cancer, and nasopharyngeal carcinoma. Now, immunotherapy covers nearly all stages of treatment for cancer patients, encompassing adjuvant/neoadjuvant treatment for early-stage tumors, consolidation treatment after radical chemoradiation for locally advanced tumors, and first-line to last-line treatments for advanced tumors. Currently, most immunotherapy drugs in China are administered intravenously, and this not only requires lengthy infusion times, but also imposes significant inconveniences on patients. There is an urgent clinical need for more convenient administration methods for immunotherapy.

Independently developed by Junshi Biosciences, JS001sc injection is a subcutaneous injection based on the marketed product toripalimab injection (code: JS001) that is expected to enhance convenience for patients. The 12 indications in the JS001sc NDAs cover all currently approved indications of toripalimab injection in the Chinese Mainland.

The NDA is mainly based on the JS001sc-002-III-NSCLC Study (NCT06505837), a multi-center, open-label, randomized phase 3 clinical study led by principal investigator Professor Lin WU from Hunan Cancer Hospital. The study aimed to compare the exposure, efficacy and safety of JS001sc plus chemotherapy versus JS001 plus chemotherapy for the first-line treatment of recurrent or metastatic non-squamous non-small-cell lung cancer ("NSCLC"). The results showed that JS001sc's exposure was non-inferior to that of JS001 with comparable efficacy and safety profiles. JS001sc-002-III-NSCLC was the first phase 3 clinical study of domestic anti-PD-1 monoclonal antibody in a subcutaneous formulation. Further details will be presented at an upcoming international academic conference.

Professor Lin WU said, "The JS001sc-002-III-NSCLC study, as China's first Phase 3 clinical trial of a domestically developed PD-1 monoclonal antibody in a subcutaneous formulation, confirmed that the subcutaneous administration method achieved statistical non-inferiority in drug exposure compared with intravenous administration, while demonstrating comparable efficacy and safety. This milestone not only validates the scientific rationale behind the pharmaceutical development of the subcutaneous formulation, but also provides a novel administration pathway for cancer immunotherapy at the clinical level. In the current era of holistic cancer management, treatment convenience and improved quality of life have become critical clinical priorities. The development and application of subcutaneous injection formulations are expected to significantly reduce dosing time, optimize healthcare resource allocation,

and offer new technical support for advancing hierarchical medical systems and home-based treatment management. We anticipate the early approval of the subcutaneous formulation of toripalimab, which will further enrich China's cancer immunotherapy landscape and ultimately benefit a broader population of cancer patients."

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, said, "We are excited that the NMPA has formally accepted the NDA for JS001sc covering all approved indications of TUOYI® (toripalimab). This signifies JS001sc's potential to address multiple tumor types, including NSCLC, nasopharyngeal carcinoma, esophageal cancer, renal cancer, and liver cancer. It also marks another critical milestone in expanding toripalimab's innovative and clinical value. As a subcutaneous formulation, JS001sc will substantially enhance dosing convenience, optimize patient treatment experiences, and improve long-term therapy adherence. Moving forward, we will actively advance the regulatory review process, consistently centering patient needs. Using our clinical evidence, we hope to leverage evidence-based medicine to advance high-quality development of China's cancer therapies, ultimately delivering more accessible, convenient, and high-quality treatment options to patients."

About JS001sc

JS001sc is a subcutaneous injection formulation developed by Junshi Biosciences based on the marketed product toripalimab injection (code: JS001). It is the first domestic anti-PD-1 monoclonal antibody in a subcutaneous formulation to enter the marketing application stage and is expected to bring convenient administration to patients. The 12 indications in the NDAs of JS001sc covers all currently approved indications of toripalimab injection in the Chinese Mainland.

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 over 50 drug candidates, with five therapeutic focus areas covering cancer, autoimmune, metabolic, neurological, and infectious diseases. Five of the company's products have received approvals in China and international markets, one of which is toripalimab, China's first domestically produced and independently developed anti-PD-1 monoclonal antibody. Toripalimab has been approved in over 40 countries and regions including China, the US, and Europe. During the COVID-19 pandemic, Junshi Biosciences actively shouldered the social responsibilities of a Chinese pharmaceutical company through its involvement in developing etesevimab, MINDEWEI®, and other novel therapies for the prevention and treatment of COVID-19.

With a mission of "providing patients with world-class, trustworthy, affordable, and innovative drugs," Junshi Biosciences is "In China, For Global." At present, the company boasts approximately 2,500 employees in the United States (Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc.). For more information, please visit: http://www.junshipharma.com.

Junshi Biosciences Contact Information

IR Team:

Junshi Biosciences

info@junshipharma.com

+ 86 021-6105 8800

PR Team:

Junshi Biosciences

Zhi Li

zhi_li@junshipharma.com

+ 86 021-6105 8800