Junshi Biosciences Announces Primary Endpoints Met in JS001sc's Phase 3 Study for the 1ST-line Treatment of NSQ-NSCLC

SHANGHAI, China, November 24, 2025 -- 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 JS001sc-002-III-NSCLC study has met its primary endpoints. JS001sc-002-III-NSCLC is a multi-center, open-label, randomized Phase 3 clinical study comparing toripalimab injection (subcutaneous injection) (code: JS001sc) or toripalimab injection (code: JS001) in combination with chemotherapy for the first-line treatment of recurrent or metastatic non-squamous non-small-cell lung cancer ("NSQ-NSCLC") (NCT06505837). Junshi Biosciences plans to submit a new drug application ("NDA") to the regulatory authorities in the near future.

According to data released by GLOBOCAN 2022, in 2022, China saw 1.06 million new lung cancer cases (22.0% of all new cancer cases in China) and 0.73 million lung cancer deaths (28.5% of all cancer-related deaths in China). NSCLC was the predominant subtype, accounting for approximately 85% of all lung cancer cases. Among NSCLC patients, non-squamous NSCLC constituted approximately 65% of cases.

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.

The JS001sc-002-III-NSCLC Study is a multi-center, open-label, randomized Phase 3 clinical study led by the principal investigator Professor Lin WU from Hunan Cancer Hospital. JS001sc-002-III-NSCLC is the first Phase 3 clinical study of a domestic anti-PD-1 monoclonal antibody subcutaneous formulation.

The study aims to compare the exposure, efficacy and safety of JS001sc plus chemotherapy or JS001 plus chemotherapy for the first-line treatment of recurrent or metastatic NSQ-NSCLC. The results have showed that the drug exposure of JS001sc was non-inferior to that of toripalimab injection with comparable efficacy and safety profiles. The study data will be presented at an upcoming international academic conference. Junshi Biosciences plans to communicate with the regulatory authorities and submit JS001sc's NDA for all approved indications of JS001.

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, said, "Since its launch as China's first domestically developed PD-1 antibody drug, toripalimab has secured approvals for 12 indications, benefiting a significant number of patients. In clinical practice, we observed that patients undergoing immunotherapy, either as monotherapy or combination maintenance therapy, face challenges such as frequent intravenous catheterization and time-consuming infusions. The recent success of the Phase 3 study for JS001sc, achieved through the efforts of both patients and the research team, marks not only a pivotal breakthrough in transitioning I-O therapy from 'efficacy' to 'convenience', but also exemplifies Junshi Biosciences' patient-centric ambition. By innovating drug delivery methods, we enhance treatment

accessibility: simplifying procedures for patients, reducing their healthcare burden, and alleviating pressure on medical resources. We are committed to advancing the registration of JS001sc and providing more patients with a better treatment experience alongside clinical benefits."

About JS001sc

JS001sc, developed by Junshi Biosciences, is a subcutaneous injection formulation based on the marketed product, toripalimab injection. JS001sc is the first domestic anti-PD-1 monoclonal antibody subcutaneous formulation to enter Phase 3 clinical study, and will potentially offer more convenient administration to patients. As of today, a multi-center, open-label, randomized Phase 3 clinical study comparing JS001sc plus chemotherapy or toripalimab injection plus chemotherapy for the first-line treatment of recurrent or metastatic NSQ-NSCLC (the JS001sc-002-III-NSCLC Study) has met its primary endpoints.

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.

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