Junshi Biosciences Announces Acceptance of the Supplemental New Drug Application of Toripalimab (Subsutaneous Injection) for the 1st-Line Treatment of HER2-Expressing Urothelial Carcinoma

SHANGHAI, China, October 28, 2026 (GLOBE NEWSWIRE) -- 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 supplemental new drug application for the company's product, toripalimab injection (subcutaneous injection) (code: JS001sc) in combination with disitamab vedotin for the treatment of HER2-expressing (HER2 expression is defined as HER2 immunohistochemistry results of 1+, 2+, or 3+) locally advanced or metastatic urothelial carcinoma (UC) has recently been accepted by the China National Medical Products Administration (NMPA). To date, the new drug application for JS001sc, in respect of all 13 approved indications of toripalimab (intravenous injection) (code: JS001), have been accepted.

JS001sc is a subcutaneous injection formulation developed by Junshi Biosciences based on the marketed product, toripalimab injection. It is the first domestic anti-PD-1 monoclonal antibody in a subcutaneous formulation to enter the new drug application stage, and is expected to bring convenient administration to patients.

Immuno-oncology (I-O) therapies, represented by anti-PD-1 monoclonal antibodies, have become cornerstone therapies for the treatment of various malignant tumors. However, immuno-oncology drugs currently available in China are predominantly formulated for intravenous infusion, which not only requires prolonged infusion times but also causes significant inconvenience to patients during treatment. Consequently, there is an urgent clinical need to improve the convenience of immunotherapy.

In November 2025, a multi-center, open-label, randomized controlled Phase 3 clinical study to compare JS001sc and toripalimab injection in combination with chemotherapy for the first-line treatment of recurrent or metastatic non-squamous non-small cell lung cancer met the primary endpoint.

In March 2026, the Phase 3 clinical study of JS001sc in combination with chemotherapy as a first-line treatment for non-squamous non-small-cell lung cancer was successfully selected for an oral presentation at the European Lung Cancer Congress 2026 (ELCC 2026). The study results demonstrated that the drug exposure of toripalimab subcutaneous injection was non-inferior to that of the intravenous formulation of toripalimab, with comparable clinical efficacy and safety profiles, and is expected to provide patients with a new, more convenient immunotherapy option.

In March 2026, the new drug application of JS001sc for 12 indications for the treatment of tumors was accepted by the NMPA, making it the first domestic anti-PD-1 monoclonal antibody in a subcutaneous formulation to enter the new drug application stage.

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. With our outstanding capacity for innovative drug discovery, strong biotechnology R&D capability, and large-scale production capacity, we have successfully developed a drug candidate portfolio with global competitiveness and a well-structured research pipeline, which covers therapeutic areas including cancer, autoimmune, metabolic, and infectious diseases. Our innovative field spans cutting-edge therapeutic modalities, including mAbs, small-molecule drugs, ADCs, bsAb/msAb, fusion proteins, nucleic acid drugs and vaccines. Five of the company's products have received marketing authorizations in China and international markets, one of which is toripalimab, China's domestically developed anti-PD-1 monoclonal antibody. Toripalimab has been approved in over 50 countries and regions including China, the US, and Europe.

With a mission of "providing patients with world-class, trustworthy, affordable, and innovative drugs," Junshi Biosciences is "In China, For Global." The company currently employs more than 3,000 people worldwide. Headquartered in Shanghai, China, it has a business presence in multiple countries and regions around the world. For more information, please visit: http://www.junshipharma.com.

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