Junshi Biosciences Announces Dosing of First Patient in Phase I Study of Anti-TROP2 Antibody - TUB196 Conjugate

Shanghai, China, November 25, 2020 -- Junshi Biosciences (HKEX: 1877; SSE: 688180), an innovation-driven biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies, is pleased to announce that the Phase I clinical study (NCT04601285) of a recombinant humanized anti-TROP2 monoclonal antibody - Tub196 conjugate (JS108), has completed the dosing of the first patient.

JS108 is a recombinant humanized anti-TROP2 monoclonal antibody - Tub196 Conjugate. TROP2 is an important receptor expressed at high level in a variety of solid tumors (including breast cancer, gastric cancer, non-small cell lung cancer, small cell lung cancer, colon cancer and pancreatic cancer) , implicated in promoting tumor cell proliferation, tissue invasion, and metastasis. Overexpression of TROP2 was correlated with poor prognosis clinically. In July 2020, JS108 clinical trial application was approved by the National Medical Products Administration (NMPA).

In recent years, antibody drug conjugates (ADCs) targeting cell surface receptors expressed on tumor cells have become treatment options for multiple cancer indications. Unlike non-specific chemotherapy, ADCs are designed to target and kill tumor cells while sparing normal healthy cells.

Junshi has entered an exclusive license agreement with Hangzhou DAC Biotech Co., Ltd. (“Hangzhou DAC”), to develop and commercialize JS108 (anti-TROP2-ADC) in Asian countries and regions excluding Japan and South Korea.

About NCT04601285 Study

NCT04601285 is an open label, first-in-human phase I clinical study to evaluate the safety, tolerability, PK profile and efficacy of JS108 in patients with advanced solid tumors. The primary endpoints for this study are safety and tolerability, while the secondary endpoints include PK profile, immunogenicity, efficacy and correlation with TROP2 protein expression level. The study consists of three stages: the dose escalation, the dose expansion, and the indication expansion. The planned enrollments in three stages are 16 to 36, 12 to 27 and 60 to 90 patients with advanced solid tumors.

About Junshi Biosciences

Founded in December 2012, Junshi Biosciences (HK: 1877; SH: 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 26 innovative drug candidates and 2 biosimilars, with five therapeutic focus areas covering cancer, autoimmune, metabolic, neurologic, and infectious diseases. Junshi Biosciences was the first

Chinese pharmaceutical company to obtain marketing approval for PD-1 monoclonal antibody in China and clinical trial application approval for PCSK9 monoclonal antibody from the NMPA. The world's first-in-human, first-in-class BTLA blocking antibody for solid tumors is currently in phase I clinical trials in the US and China. In early 2020, Junshi Biosciences joined forces with Institute of Microbiology Chinese Academy of Science and Eli Lilly to co-develop JS016, China's first neutralizing fully human monoclonal antibody against SARS-CoV-2, which has entered clinical trials and is now a part of our continuous innovation for disease control and prevention of the global pandemic. Junshi Biosciences have about 2,000 full time employees in the United States and China, including research and development centers in San Francisco, Maryland, Shanghai, Suzhou, Beijing and Guangzhou. For more information, please visit: http://junshipharma.com.