Junshi Biosciences Announces Completion of Enrollment in Phase I Trial of SARS-CoV-2 Neutralizing Antibody JS016 in China

SHANGHAI, China, July 12, 2020 -- Junshi Biosciences (HKEX: 1877), a leading innovation-driven biopharmaceutical company dedicated to the discovery, development, and commercialization of novel therapies, announced today the completion of study subjects enrollment in Phase I trial of SARS-CoV-2 neutralizing monoclonal antibody injection (Product Code: JS016), developed jointly with Institute of Microbiology, Chinese Academy of Sciences (IMCAS). JS016 is the first COVID-19 neutralizing antibody entering clinical trials in China. It also entered in clinical trials in the US during the second quarter.

The study is a randomized, double-blind, placebo-controlled Phase I trial led by Prof. Zhang Jing and Prof. Zhang Wenhong from Huashan Hospital Affiliated to Fudan University, aiming to investigate the safety and tolerability of single dose JS016 intravenous injection (IV) in 40 healthy subjects (including both male and female). JS016 is the first neutralizing antibody entering clinical trial in healthy subjects in the world. The study enrolled the first patient on June 7th, and completed dosing in all 40 subjects in 4 dosing groups. No dose-limiting event (DLE) has been observed as of July 12th.

Junshi Biosciences plans to initiate Phase Ib trial in non-severe COVID-19 patients and Phase II/III trials in severe and critical patients soon. Simultaneously, the company will investigate the prophylactic potential of JS016 in high-risk population.

COVID-19 is an acute respiratory infectious disease caused by the SARS-CoV-2 virus that has infected more than 12 million people, with a current death toll of over 560,000 worldwide. There are currently no approved vaccines or specific drugs that target COVID-19.

About JS016

JS016 is specific to the SARS-CoV-2 surface spike protein receptor binding domain and can effectively block the binding of viruses to host cell surface receptor ACE2. The project is jointly developed by Junshi Biosciences and Institute of Microbiology, Chinese Academy of Science.

At the beginning of the COVID-19 outbreak, Junshi Biosciences rapidly launched the research and development program of neutralizing antibodies to combat COVID-19. Within two months, the company has completed IND enabling pre-clinical studies, the process development and production for GLP toxicity study and GMP production of clinical material by leveraging the company's platform technology.

JS016 is in Phase I trial in China, which is the first clinical trial of a SARS-CoV-2 neutralizing antibody in healthy subjects in the world.

About Junshi Biosciences

Established in 2012, Junshi Biosciences is committed to developing first-in-class and best-in-class drugs through original innovation and becoming a pioneer in the area of translational medicine to provide patients with effective and affordable treatment options. On December 24, 2018, Junshi Biosciences was listed on the Main Board of the Stock Exchange of Hong Kong with the stock code:

1877.HK. The Company has established a diversified R&D pipeline comprising 21 drug candidates with therapeutic areas covering cancer, metabolic diseases, autoimmune diseases, neurologic diseases, and Infectious disease. Product types include monoclonal antibodies, fusion proteins, antibody-drug conjugates, and small molecule drugs. With a combined 33,000L fermentation capacity in two GMP-facilities at Shanghai and Suzhou, Junshi has established the manufacturing infrastructure to support commercialization and provide our partners and patients with high-quality products through a global supply chain network. For more information, please visit: http://junshipharma.com.