News Release

IND of Junshi Biosciences' FIH anti-BTLA Antibody for Cancer Treatment Approved by NMPA

Junshi Biosciences is pleased to announce that the company has received the Clinical Trial Approval in respect of the "recombinant humanized anti-BTLA monoclonal antibody injection" (project code: TAB004/JS004) issued by the National Medical Products Administration (NMPA).

JS004 is the world's first anti-BTLA monoclonal antibody for cancer treatment approved for clinical trial. It is also the second drug candidate independently developed by Junshi Biosciences that obtained IND approval both from China National Medical Products Administration (NMPA) and the U.S. Food and Drug Administration (FDA) after toripalimab, of which the company owns complete independent intellectual property rights. Currently, there are no products with similar targets on the market.

Pre-clinical studies have shown that JS004 can promote tumor-specific T cells proliferation, enhance lymphocyte function, reduce tumor burden and increase survival rates in a BTLA humanized mouse tumor model. When combined with toripalimab, TAB004 could further enhance the proliferation of tumor-specific T cells and the production of anti-tumor cytokines, offering more options for combination therapy.

In April 2019, the IND of JS004 for treatment of patients with advanced unresectable or metastatic solid tumors (including lymphoma) and patients refractory to prior PD-1 antibody treatment was approved by the U.S. FDA for clinical trial. In October 2019, the first patient has been successfully dosed in the Phase I clinical trial (NCT04137900) conducted in the U.S.

About anti-BTLA Monoclonal Antibody Injection (TAB004/JS004)

BTLA is an immunoglobulin (Ig) receptor family member identified in 2003. **HVEM** (a counter receptor for BTLA) is expressed on a variety of tumor cells including NSCLC, melanoma, colorectal cancer and lymphomas. Tumor expression of HVEM has been associated with poor prognosis and immune escape.

Study revealed that BTLA is expressed at high levels on tumor specific CTLs and inhibits T cell function upon engagement by tumor expressed HVEM, suggesting BTLA blockade might potentially improve T cell function and anti-tumor immunity.

Importantly, coblockade of BTLA and PD-1 pathways increased the frequency and effector cytokine production of melanoma specific CTLs, whereas either BTLA or PD-1 blockade alone had limited effect, suggesting BTLA pathway is a potential resistance mechanism for patients refractory to anti-PD-1 monotherapy.

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In vitro and in vivo studies have shown TAB004 or JS004 can promote antigen specific T cell proliferation and effector function, reduce tumor burden and improve survival in human BTLA knock-in tumor models.

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About Junshi Biosciences

Junshi Biosciences (NEEQ:833330; HKEx:1877) was founded in December 2012 by a team graduated from renowned universities in China and the United States with extensive experience in the industry and international transfer of technology.

Junshi Biosciences is mainly engaged in the research and development of therapeutic antibodies. The company specializes in the R&D and industrialization of innovative monoclonal antibody drugs and other therapeutic proteins (TPs) drugs. With an impressive product pipeline including 18 innovative drugs and 2 biosimilars, Junshi Biosciences is the first Chinese company to achieve marketing approval for anti-PD-1 monoclonal antibody in China. It is also the first company in China to have obtained approval for IND application for anti-PCSK9 mAb and anti-BLyS mAb from NMPA. Its world's first-in-human anti-BTLA mAb has obtained IND approval from both China NMPA and the U.S. FDA for tumor treatment. Junshi Biosciences has more than 1000 employees in San Francisco and Maryland in the U.S., and Shanghai, Suzhou, Beijing and Guangzhou in China.

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Official Website：www.junshipharma.com