Junshi Biosciences Announces Updated Clinical data from Phase I study of anti-BTLA antibody Tifcemalimab in Treatment of Relapsed/Refractory Lymphomas at 64th ASH Annual Meeting

-- Preliminary study results show that tifcemalimab is well-tolerated at all administered doses. The observed clinical activity of tifcemalimab in combination with toripalimab in lymphoma patients refractory to checkpoint inhibitors warrants further evaluation. Combination dose expansion is under way.

--Among the 28 evaluable patients who received the combination regimen, while 85.7% of the patients progressed upon prior anti-PD-1, 39.3% achieved ORR, and median DoR has not yet been reached.

SHANGHAI, China, December 10, 2022 (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 today that the updated preliminary data from a Phase I study of tifcemalimab as a single agent or in combination with toripalimab in relapsed/refractory lymphomas in a poster at the 64th American Society of Hematology (ASH) Annual Meeting. Tifcemalimab is the world's first-in-human anti-tumor anti-BTLA monoclonal antibody independently developed by the company.

"Nowadays, PD-1 inhibitors are widely used in the treatment of lymphomas, particularly relapsed or refractory classical Hodgkin's lymphoma (R/R cHL)," said Dr. Yuqin Song of Peking University Cancer Hospital and Institute. "However, if PD-1 inhibitors fail, there is no standard treatment to resort to, thus new treatment methods are urgently needed in clinical practice. Through research, we have discovered that these types of patients can expect to benefit once again when treated with tifcemalimab and toripalimab combined. We've also observed a similar advantage in this treatment method as well as other immune checkpoint inhibitors—both may bring long-term survival benefits to patients. As the clinical trials continue, we look forward to observing tifcemalimab's performance and the new treatment options it can bring to more lymphoma patients."

"The first of its kind in the entire world, tifcemalimab exhibits promising safety and efficacy in early clinical trials", said Dr. Jianjun Zou, Global Research and Development President at Junshi Biosciences. "In particular, the updated research data released at the ASH Annual Meeting highlights that the tifcemalimab-toripalimab dual immunotherapy is promising for patients with relapsed/refractory lymphoma resistant to anti-PD-1 monoclonal antibodies, and is worth further evaluation. Apart from that, we've also seen its outstanding safety and efficacy in patients with solid tumors, and are eager for further verification in subsequent research."

The study is a single-arm, open-label, multicenter, dose-escalation phase I study (NCT0447772) evaluating the safety and efficacy of tifcemalimab as a single agent or in combination with toripalimab in relapsed/refractory lymphomas. This is the very first time an anti-BTLA antibody was evaluated for safety and efficacy in the treatment of lymphomas. Earlier this year in June, tifcemalimab made its debut with preliminary data from the clinical trials at the American Society of Clinical Oncology (ASCO) annual meeting, creating a milestone for all BTLA-targeting drugs in the field of cancer. Now, updated results from the clinical trial for lymphomas have been presented at the ASH annual meeting. The leading PI of this study include Dr. Jun Ma from Harbin Institute of Hematology and Oncology and Dr. Jun Zhu from Peking University Cancer Hospital and Institute, with Dr. Yuqin Song as the presenting author.

By the cutoff date of October 26, 2022, a total of 63 patients with relapsed/refractory lymphoma were enrolled in the study, including 43 patients with Hodgkin's lymphoma (HL) and 20 with non-Hodgkin's lymphoma (NHL). Among the 25 evaluable patients who received monotherapy, 9 received monotherapy dose escalation and 16 received monotherapy dose expansion; among the 38 patients who received combination treatment, 6 received combination dose escalation and 32 received combination dose expansion. Patients were heavily treated with median 4 prior lines of therapy. 46 patients (73.0%) received prior anti-PD-1/L1 therapy.

In terms of safety and tolerability, as of October 26, 2022, no dose-limiting toxicity (DLT) was observed in either monotherapy or combination dose escalation. Additionally, the immune related adverse event (irAE) profile of the combination was consistent with toripalimab monotherapy, and no novel safety signals were identified in the combination cohorts.

Regarding clinical anti-tumor actitivity, as of October 26, 2022, the median follow-up was 29.1 weeks, 1 case of partial remission (PR) and 7 cases of stable disease (SD) were observed among the 25 evaluable patients receiving monotherapy. Among the 28 evaluable patients receiving the combination regimen, 24 (85.7%) patients progressed upon prior anti-PD-1, and 1 complete response (CR), 10 PR, and 13 SD were observed. The objective response rate (ORR) reached 39.3% and the disease control rate (DCR) reached 85.7%. All patients with CR/PR responses in the combination groups are ongoing by the cutoff date and the median duration of response (DoR) is not yet reached.

About Tifcemalimab (JS004/TAB004)

Tifcemalimab is the world’s first-in-human recombinant humanized anti-BTLA (B- and T-lymphocyte attenuator) monoclonal antibody independently developed by Junshi Biosciences. So far, tifcemalimab has entered phase Ib/II study, and several trials of tifcemalimab in combination with toripalimab in patients with different types of tumors are ongoing in China and the United States.

In 2003, B and T lymphocyte attenuator (BTLA), the target of tifcemalimab was discovered. It is a member of the CD28 receptor family. It has a single IgSF V extracellular domain; its sequence is similar to other molecules of the CD28 family (such as PD-1 and CTLA-4).

BTLA is expressed in the T lymphocyte, B lymphocyte and dendritic cell subpopulations. In 2005, the interaction between BTLA and its ligand, Herpes virus entry mediator (HVEM) was discovered. HVEM is a TNF receptor extensively expressed in the hematopoietic system and is confirmed as the ligand of BTLA.

BTLA is an immunoglobulin associated membrane protein; its protein structure is similar to that of the transmembrane receptors (CTLA-4 and PD-1). Under normal physiological conditions, after BTLA binds with its ligand HVEM, the over-activation of lymphocytes in the human body is inhibited, thus avoiding autoimmune injuries.

By binding with BTLA, tifcemalimab blocks the HVEM-BTLA interaction, thereby obstructing the BTLA-mediated inhibitory signal pathways and activating the tumor specific lymphocytes.

Tifcemalimab interferes with the HVEM-BTLA interaction by binding to BTLA, thus blocking the inhibitory signal pathway mediated by BTLA and resulting in the activation of tumor-specific lymphocytes.

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. Junshi Biosciences was the first Chinese pharmaceutical company that obtained marketing approval for anti-PD-1 monoclonal antibody in China. Its first-in-human anti-BTLA monoclonal antibody for the treatment of various cancers was the first in the world to be approved for clinical trials by the FDA and NMPA and has since entered Phase Ib/II trials in both China and the US. Its anti-PCSK9 monoclonal antibody was the first in China to be approved for clinical trials by the NMPA.

In the face of the pandemic, Junshi Biosciences' response was strong and immediate, joining forces with Chinese and international scientific research institutions and enterprises to develop an arsenal of drug candidates to combat COVID-19, taking the initiative to shoulder the social responsibility of Chinese pharmaceutical companies by prioritizing and accelerating COVID-19 R&D. Among the many drug candidates is JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 and the result of the combined efforts of Junshi Biosciences, the Institute of Microbiology of the Chinese Academy of Science and Lilly. JS016 administered with bamlanivimab has been granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. Meanwhile, VV116, a new oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, is in global Phase

III clinical trials. The JS016 and VV116 programs are a part of the company's continuous innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has more than 3,100 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing and Guangzhou). For more information, please visit: http://junshipharma.com.

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