JUPITER-02 Phase III Global Study of Toripalimab at the Interim Analysis Met Pre-Specified Primary Endpoint of Progression-Free Survival in Recurrent or Metastatic Nasopharyngeal Carcinoma

Shanghai, China, September 29, 2020 (GLOBE NEWSWIRE) -- 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 an Independent Data Monitoring Committee (IDMC) determined that the randomized, double-blind, placebo- controlled, international multi-center Phase III study JUPITER-02 at the interim analysis had met its pre-specified primary endpoint. The results of the study showed that Toripalimab in combination with Gemcitabine/Cisplatin as a first-line treatment for patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) significantly extended the progression-free survival than the current standard treatment of Gemcitabine/Cisplatin. The Company will submit biologic license application (BLA) to the National Medical Products Administration (the “NMPA”) and regulatory authorities in other relevant countries in the near future.

About NPC

Nasopharyngeal carcinoma (NPC), a subtype of head and neck cancer, is a malignant tumor that occurs in the nasopharynx. According to statistics from the World Health Organization, NPC is widely distributed in Southeast Asia and the incidence in the region accounts for approximately 84.6% of the new cases worldwide. NPC is prone to distant metastasis at diagnosis, while early stage patients tend to relapse after radiation or radio-chemotherapy. Platinum-based therapy is currently standard care for recurrent or metastatic NPC. In addition, there is no standard treatment after failure of the firs-line systemic chemotherapy. The 5-year overall survival rate of patients with advanced disease is less than 10%.

ABOUT JUPITER-02 STUDY

The JUPITER-02 Study (NCT03581786) is a randomized, double-blind, placebo-controlled, international multi-center Phase III clinical study to compare the efficacy and safety of Toripalimab versus placebo in combination with Gemcitabine/Cisplatin, as a first-line treatment for patients with recurrent or metastatic nasopharyngeal carcinoma. Professor Xu Ruihua from Sun Yat-sen University Cancer Centre is the leading principal investigator. The JUPITER-02 Study enrolled a total of 289 patients. The primary endpoint of the study is progression-free survival (PFS), and the secondary endpoints include overall survival (OS), objective response rate (ORR), duration of response (DOR), disease control rate (DCR) and safety.

At the interim analysis, the Independent Data Monitoring Committee (IDMC) determined that the global study met its primary endpoint of progression free survival (PFS). Compared with the placebo control, Toripalimab in combination with Gemcitabine/Cisplatin significantly prolonged the PFS as a first-line treatment for patients with recurrent or metastatic nasopharyngeal carcinoma.

About Toripalimab

Toripalimab is a PD-1 monoclonal antibody developed by Junshi Biosciences. Toripalimab received its first approval for 2nd line treatment of metastatic melanoma on December 17, 2018 in China and was commercially launched in February 2019. More than 30 clinical studies covering more than ten cancer indications have been conducted in China, the United States and other countries.

In April 2020, the supplemental New Drug Application ("NDA") of Toripalimab for the treatment of recurrent/metastatic nasopharyngeal carcinoma after failure of at least two prior systemic treatments has been accepted by the NMPA. This supplemental NDA is the world's first NDA of PD-1 blockade therapy for the treatment of nasopharyngeal carcinoma. In May 2020, the supplemental NDA of Toripalimab for the treatment of locally advanced or metastatic urothelial carcinoma after systemic treatment has been accepted by the NMPA. Both supplemental NDAs received priority review status by the NMPA in July 2020.

In March 2020, Toripalimab in combination with axitinib for the treatment of mucosal melanoma was granted the orphan-drug designation by the US FDA. In May and September 2020, Toripalimab also received the orphan-drug designation by the FDA for the treatment of nasopharyngeal carcinoma and soft tissue sarcoma. In September 2020, Toripalimab for the treatment of nasopharyngeal carcinoma was granted the Breakthrough Therapy designation by the FDA.

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 areas covering cancer, autoimmune, metabolic, neurologic, and infectious diseases. Junshi Biosciences was the first Chinese pharmaceutical company that obtained marketing approval for PD-1 monoclonal antibody in China. The world's first-in-human anti-BTLA antibody for solid tumors was approved for clinical trials by the FDA and NMPA in 2019. Amid the global Covid-19 pandemic, Junshi Biosciences in collaboration with Institute of Microbiology of Chinese Academy of Science, developed China's first neutralizing monoclonal antibodies against SARS-Cov-2, which started clinical trial in June 2020. Junshi Biosciences currently have about 2,000 full time employees in Shanghai, Suzhou, Beijing, and Guangzhou, China, as well as San Francisco and Maryland in the US. For more information, please visit: http://junshipharma.com.