Junshi Biosciences Announces Acceptance of the Supplemental NDA for Toripalimab in Combination with Chemotherapy for Advanced Triple-negative Breast Cancer

SHANGHAI, China, May 23, 2023 (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 that the National Medical Products Administration ("NMPA") has accepted the supplemental new drug application ("sNDA") for the company's anti-PD-1 monoclonal antibody, toripalimab, used in combination with albumin-bound paclitaxel for the treatment of PD-L1 positive (CPS ≥ 1) untreated metastatic or recurrent metastatic triple-negative breast cancer ("TNBC").

According to GLOBOCAN 2020, breast cancer exhibited the highest incidence rates worldwide, with 2.26 million new cases and 0.68 million deaths in 2020. In China, 0.42 million new cases and 0.12 million deaths due to breast cancer were reported in 2020, accounting for 18.4% and 17.1% of global cases, respectively. Amongst these breast cancer cases, approximately 10% to 15% were classified as TNBC. TNBC is a more aggressive type of cancer with a higher risk of recurrence and a poor prognosis. Unfortunately, advanced TNBC does not respond well to targeted therapy and endocrine therapy, and there are currently no specific treatment methods available.

In recent years, clinical studies have shown that immunotherapy in combination with chemotherapy for the treatment of advanced TNBC can achieve better efficacy and tolerability. To this day, however, no immunotherapy drugs have been approved for advanced TNBC in China, and chemotherapy remains the primary treatment option. Alternative drugs include anthracyclines, taxanes, platinum-based drugs, etc. Both mono-chemotherapy and combination chemotherapy have poor efficacy, with a median survival time of about 9 to 12 months and a 5-year survival rate of less than 30%.

The supplemental new drug application is based on the TORCHLIGHT study (NCT04085276), which is a randomized, double-blind, placebo-controlled, multi-center Phase III clinical study jointly conducted across 56 centers nationwide, with Professor Zefei JIANG from the Department of Oncology of the Chinese People's Liberation Army General Hospital and Vice President and Secretary General of the Chinese Society of Clinical Oncology (CSCO), serving as the principal investigator. The study was designed to compare the efficacy and safety of toripalimab combined with albumin-bound paclitaxel versus placebo combined with albumin-bound paclitaxel in patients with an initial diagnosis of stage IV or recurrent metastatic TNBC. In February 2023, the Independent Data Monitoring Committee (IDMC) determined in an interim analysis that the primary endpoint of the TORCHLIGHT study had met its pre-defined efficacy boundary.

TORCHLIGHT study is the first domestic Phase III registered study to achieve positive results in advanced TNBC immunotherapy. The study results showed that, compared with albumin-bound paclitaxel alone, toripalimab in combination with albumin-bound paclitaxel in patients with an initial diagnosis of stage IV or recurrent metastatic triple-negative breast cancer could significantly prolong the progression-free survival ("PFS") of PD-L1 positive patients. Meanwhile, the overall survival ("OS"), one of the secondary endpoints, also showed a clear trend of improvement in PD-1 positive patients as well as in all patients, regardless of PD-1 status. The safety profile of toripalimab is consistent with known checkpoint

inhibitor-related risks, and no new safety signals were identified.

Details of the TORCHLIGHT results will be published in the form of a "Late-breaking Abstract (LBA)" (#LBA1013) oral presentation during the rapid abstract session at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.

"Over 2 million breast cancer cases occur annually, making it the most prevalent cancer worldwide," said Professor Zefei JIANG from the Department of Oncology of the Chinese People's Liberation Army General Hospital. "While advancements in breast cancer treatment have continued to improve patient prognosis, TNBC remains a challenging subtype characterized by its aggressive nature and poor prognosis. Effective treatment methods for TNBC are still lacking, and the 5-year survival rate for advanced TNBC patients falls below 30%. In our TORCHLIGHT study, we combined chemotherapy with an immune checkpoint inhibitor, which resulted in significantly prolonged PFS in TNBC patients, along with other significant survival benefits. I am delighted to see the acceptance of the NDA for toripalimab in combination with chemotherapy for the treatment of advanced TNBC. I eagerly anticipate its approval as it will provide better treatment options for TNBC patients in China!"

"For a very long time, the treatment of advanced TNBC has been incredibly challenging, and TNBC has posed a constant threat to patients' lives," said Dr. Jianjun ZOU, the Global Research and Development President of Junshi Biosciences. "We at Junshi Biosciences have remained steadfast in our patient-centric approach and successfully collaborated with researchers on the TORCHLIGHT study, which has demonstrated significant improvements in PFS and OS. We plan to work closely with regulatory authorities to expedite the approval process and address the unmet needs of countless TNBC patients in China as soon as possible."

About Toripalimab

Toripalimab is an anti-PD-1 monoclonal antibody developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2, and for enhanced receptor internalization (endocytosis function). Blocking PD-1 interactions with PD-L1 and PD-L2 promotes the immune system's ability to attack and kill tumor cells.

More than forty company-sponsored toripalimab clinical studies covering more than fifteen indications have been conducted globally by Junshi Biosciences, including in China, the United States, Southeast Asia, and Europe. Ongoing or completed pivotal clinical trials evaluating the safety and efficacy of toripalimab cover a broad range of tumor types, including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney and skin.

In China, toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing (approved in China as TUOYI®). Currently, there are six approved indications for toripalimab in China:

1. unresectable or metastatic melanoma after failure of standard systemic therapy;
2. recurrent or metastatic nasopharyngeal carcinoma ("NPC") after failure of at least two lines of prior systemic therapy;

3. locally advanced or metastatic urothelial carcinoma that failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy;
4. in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic NPC;
5. in combination with paclitaxel and cisplatin in first-line treatment of patients with unresectable locally advanced/recurrent or distant metastatic esophageal squamous cell carcinoma ("ESCC");
6. in combination with pemetrexed and platinum as the first-line treatment in EGFR mutation-negative and ALK mutation-negative, unresectable, locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC).

The first three indications have been included in the National Reimbursement Drug List (NRDL) (2022 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma.

In the United States, the Biologics License Application (BLA) for toripalimab in combination with gemcitabine/cisplatin for the first-line treatment of patients with advanced recurrent or metastatic NPC and toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy is under review by the U.S. Food and Drug Administration ("FDA"). The FDA has granted Breakthrough Therapy designations for toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC as well as for toripalimab monotherapy in the second or third-line treatment of recurrent or metastatic NPC. Additionally, the FDA has granted Fast Track designation for toripalimab for the treatment of mucosal melanoma and Orphan Drug designations for the treatment of esophageal cancer, NPC, mucosal melanoma, soft tissue sarcoma, and small cell lung cancer (SCLC).

In Europe, marketing authorization applications (MAA) were accepted by the European Medicines Agency (EMA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) for 1) toripalimab combined with cisplatin and gemcitabine for the first-line treatment of patients with locally recurrent or metastatic NPC and 2) toripalimab combined with paclitaxel and cisplatin for the first-line treatment of patients with unresectable locally advanced/recurrent or metastatic ESCC, in December 2022 and February 2023.

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 an 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. In 2021, JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 administered with bamlanivimab, was granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. Meanwhile, VV116 (deuremidevir hydrobromide), a novel oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, has been approved for marketing in China and Uzbekistan. The JS016 and VV116 programs are a part of the company's continuous efforts towards innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has about 3,000 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc.). For more information, please visit: http://junshipharma.com.

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