Junshi Biosciences Announces Approval of the Supplemental New Drug Application for Toripalimab as Perioperative Treatment for Resectable NSCLC Patients

SHANGHAI, China, January 2, 2024 (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 supplemental new drug application (the "sNDA") for toripalimab (trade name: TUOYI®, product code: JS001) in combination with chemotherapy as perioperative treatment and subsequently, monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage IIIA-IIIB non-small cell lung cancer ("NSCLC") has been approved by the National Medical Products Administration. This is the first approved perioperative therapy for lung cancer in China and the second worldwide.

Lung cancer is currently the world's second most prevalent malignant tumor, with the highest mortality rate. According to the World Health Organization, in 2020, the number of new lung cancer cases in China amounted to 816,000, accounting for 17.9% of all new cancer cases in China. In the same year, the number of lung cancer deaths in China amounted to 715,000, accounting for 23.8% of all cancer deaths in China. NSCLC is a major subtype of lung cancer, accounting for approximately 85% of all cases. Amongst these patients, 20%-25% are surgically resectable at first diagnosis, but even after radical surgical treatment, 30%-55% of these patients suffer from post-surgical recurrence and death. Radical surgery in combination with chemotherapy is a way to prevent recurrence, but chemotherapy alone, as preoperative neoadjuvant or postoperative adjuvant therapy, has limited clinical benefits and can only raise patients' 5-year survival rate by approximately 5%.

The approval of the sNDA is primarily based on data from the NEOTORCH study (NCT04158440), a randomized, double-blind, placebo-controlled, multi-center phase III clinical study led by Professor Shun LU of Shanghai Chest Hospital of the Shanghai Jiao Tong University School of Medicine. Conducted across 56 centers nationwide, NEOTORCH is the world's first phase III clinical study of anti-PD-1 monoclonal antibody for NSCLC perioperative treatment (including neoadjuvant and adjuvant) with positive event-free survival ("EFS") results.

A total of 404 patients with stage IIIA-IIIB NSCLC were enrolled in the study and randomized at a ratio of 1:1 to receive toripalimab in combination with chemotherapy (n=202) or placebo in combination with chemotherapy (n=202). The patients received three cycles of pre-operative treatment and one cycle of post-operative treatment with toripalimab or placebo in combination with chemotherapy (paclitaxel in combination with cisplatin for patients with squamous NSCLC, while pemetrexed in combination with cisplatin for patients with non-squamous NSCLC), respectively; they then received either toripalimab or placebo for 13 cycles of adjuvant therapy.

The latest study results of the NEOTORCH study were announced in an oral presentation at the 2023 American Society of Clinical Oncology ("ASCO") Plenary Series held in April, as well as the 2023 ASCO annual meeting. The study data showed that compared to chemotherapy alone, toripalimab in combination with chemotherapy for perioperative treatment of resectable stage III NSCLC could significantly extend patient EFS (median EFS as assessed by investigators: not reached vs. 15.1 months, $P < 0.0001$), and reduce the risk of disease recurrence, progression, or death in patients by 60% (HR=0.40, 95% CI: 0.277-0.565), and EFS benefits was observed in all key toripalimab subgroups, regardless of PD-

L1 expression status and histologic type (squamous or non-squamous). Major pathological remission (MPR) rates and pathological complete remission (pCR) rates were significantly better in the toripalimab group, 48.5% vs 8.4% (P < 0.0001) and 24.8% vs 1.0% (P < 0.0001), respectively, and the overall survival (OS) of the toripalimab group also showed a clear trend of benefit. In terms of safety, the incidences of treatment-emergent adverse events (TEAEs) were similar in both groups, and no new safety signals were observed.

“The NEOTORCH study has pioneered the world’s first ‘3+1+13’ perioperative treatment model for NSCLC, which has resulted in nearly 25 times higher rates of pCR and 6 times higher rates of MPR compared to patients treated with chemotherapy alone,” said, Professor Shun LU of Shanghai Chest Hospital of the Shanghai Jiao Tong University School of Medicine. “Additionally, this model has achieved elevated rates of R0 resection without increasing the surgical risks. Post-surgery, this regimen requires one cycle of immunotherapy combined with chemotherapy, along with a year-long maintenance treatment with toripalimab, which further eliminates patients’ residual lesions and extends benefits to those who did not achieve pCR. The EFS hazard ratio (HR) of 0.40 stands as the most substantial reduction in HR reported in perioperative immunotherapy studies to date. We believe that the approval of China’s first perioperative immunotherapy indication for lung cancer will significantly impact the long-term survival prospects for stage III NSCLC patients in China, opening up new avenues for potential treatments, drastically improving the standard of NSCLC treatment in China, and setting a new benchmark for perioperative treatment.”

“This approval of the new perioperative lung cancer indication signifies the expansion of toripalimab’s treatment population from late-stage to early-stage cancer patients. One of the first domestic pharmaceutical companies to initiate clinical trials for perioperative immunotherapy, Junshi Biosciences entered the perioperative immunotherapy arena very early on and now holds the broadest spectrum of indications in China. Presently, cancer immunotherapy has evolved into the standard treatment for various late-stage cancers, we are confident that this innovative therapy will lead to breakthrough changes in early cancer treatment and become the preferred treatment option for patients seeking long-term benefits," said Dr. Jianjun ZOU, Global Research and Development President of Junshi Biosciences.

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 seven 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);
7. in combination with chemotherapy as perioperative treatment and subsequently with monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage IIIA-IIIB NSCLC.

The first six indications have been included in the National Reimbursement Drug List (NRDL) (2023 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma.

In the United States, the U.S. Food and Drug Administration (FDA) has approved the Biologics License Application for toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for toripalimab, as a single agent, for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy in October 2023. The FDA has granted toripalimab 2 Breakthrough Therapy designations for the treatment of NPC, 1 Fast Track designation for the treatment of mucosal melanoma, and 5 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.

In Australia, the new chemical entity (NCE) application was accepted by the Australia Therapeutic Goods Administration (TGA) in November 2023. The TGA has also granted toripalimab an Orphan Drug designation for the treatment of NPC.

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. Four of the company's innovations have already reached the Chinese or international markets, one of which is toripalimab, China's first domestically produced and independently developed anti-PD-1 monoclonal antibody, approved in China and the US. Additionally, more than 30 drugs are currently in clinical development. During the COVID-19 pandemic, Junshi Biosciences actively shouldered the social responsibilities of a Chinese pharmaceutical company through its involvement in developing etesevimab, MINDEWEI®, and other novel therapies for the prevention and treatment of COVID-19.

With a mission of "providing patients with world-class, trustworthy, affordable, and innovative drugs", Junshi Biosciences is "In China, For Global." At present, the company boasts approximately 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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