Junshi Biosciences Announces Publication of Results from TORCHLIGHT, a Randomized Phase 3 Trial of Toripalimab for the Treatment of Metastatic or Recurrent Triple-negative Breast Cancer in Nature Medicine

SHANGHAI, China, January 9, 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 the publication of results from TORCHLIGHT (NCT04085276), a randomized, double-blind, placebo-controlled phase 3 study comparing the efficacy and safety of toripalimab versus placebo, in combination with nab-paclitaxel for patients with newly diagnosed metastatic or recurrent locally advanced triple-negative breast cancer (TNBC) in Nature Medicine.

TORCHLIGHT is the first registered Phase 3 study to achieve positive results in advanced TNBC immunotherapy in China. It was jointly conducted across 56 centers nationwide, with principal investigator 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).

"Using immunotherapy with Chinese products and designs to address the challenges of Chinese patients with advanced TNBC, TORCHLIGHT has produced encouraging results, providing some TNBC patients with an opportunity at prolonged survival," said Professor Zefei JIANG.

From December 25, 2018, to November 30, 2022, 531 patients were enrolled and randomized at a 2:1 ratio into either the experimental arm (n = 353; treated with toripalimab and nab-paclitaxel) or the control arm (n = 178; treated with placebo and nab-paclitaxel). A total of 300 patients had PD-L1-positive TNBC: 200 in the toripalimab arm and 100 in the control arm. The primary endpoints were progression-free survival (PFS), as assessed by blinded independent central review (BICR) per RECIST v.1.1, in the PD-L1-positive subgroup and the intention-to-treat (ITT) population. The secondary endpoints included overall survival (OS) in the PD-L1-positive and ITT populations, 1-year and 2-year OS rates, PFS as assessed by the investigator, objective response rate (ORR), disease control rate (DCR), duration of response (DoR) and safety.

TORCHLIGHT's results show that the addition of toripalimab to nab-paclitaxel significantly improved PFS for PD-L1-positive patients with metastatic or recurrent TNBC, while maintaining an acceptable safety profile.

At the prespecified interim analysis (cutoff date of 30 November 2022), a statistically significant improvement in PFS assessed by BICR was demonstrated in the toripalimab arm in the PD-L1-positive population (median PFS 8.4 versus 5.6 months; hazard ratio (HR) = 0.65, 95% confidence interval (CI) 0.470–0.906, P = 0.0102), which had crossed the prespecified efficacy boundary of 0.0273. The 1-year PFS rate was 41.9% versus 24.4%, and the 2-year PFS rate was 23.5% versus 14.5%. The interim analysis of PFS in the ITT population showed a similar improvement in BICR-assessed PFS. The median PFS was 8.4 and 6.9 months for the toripalimab and control arms, respectively, and the HR was 0.77 (95% CI 0.602–0.994), P = 0.0445.

According to the prespecified descriptive analysis of OS, a trend toward improved OS favoring toripalimab was observed in the PD-L1-positive population, with median OS at 32.8 versus 19.5 months (HR = 0.62, 95% CI 0.414–0.914, nominal P = 0.0148). The 1, 2 and 3-year OS rates in the PD-L1-positive population were 82.6% versus 73.0%, 64.6% versus 43.5% and 47.9% versus 33.0% in the two arms, respectively. Similar OS improvement was also observed in the ITT population favoring toripalimab, with median OS 33.1 versus 23.5 months (HR = 0.69, 95% CI 0.513–0.932, nominal P = 0.0145). The 1, 2 and 3-year OS rates in the ITT population were 81.0% versus 77.6%, 61.0% versus 47.2% and 48.4% versus 32.1% in the two arms, respectively.

Patients in the toripalimab arm had a significantly longer DoR than those in the control arm in the PD-L1-positive subgroup and ITT populations. The median DoR was 10.8 versus 5.6 months (HR = 0.55, 95% CI 0.366–0.830, nominal P = 0.0040) in the PD-L1-positive subgroup; and 8.5 versus 6.9 months (HR 0.64, 95% CI 0.468–0.881, nominal P = 0.0060) in the ITT population.

Similar incidences of treatment-emergent adverse events (AEs) (99.2% versus 98.9%), grade ≥3 treatment-emergent AEs (56.4% versus 54.3%) and fatal AEs (0.6% versus 3.4%) occurred in the toripalimab and control arms.

In May 2023, the supplemental new drug application (sNDA) for toripalimab in combination with albumin-bound paclitaxel for the treatment of PD-L1 positive (CPS ≥ 1) previously-untreated metastatic or recurrent metastatic TNBC was accepted by the National Medical Products Administration (NMPA).

“I am delighted to see the TORCHLIGHT study reach new heights once again,” said Dr. Jianjun ZOU, Global Research and Development President of Junshi Biosciences. “TORCHLIGHT’s series of successes would not have been possible without the collaboration and determination of the patients, researchers, and R&D team. The groundbreaking outcomes of this study has the potential to address unmet clinical needs and offer Chinese TNBC patients better treatment options.”

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.

Junshi Biosciences Contact Information

IR Team:
Junshi Biosciences
info@junshipharma.com
+ 86 021-6105 8800

PR Team:
Junshi Biosciences
Zhi Li
zhi_li@junshipharma.com
+ 86 021-6105 8800