Junshi Biosciences Announces Toripalimab's NDA Accepted by the Singapore Health Sciences Authority

SHANGHAI, China, February 1, 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 Singapore Health Sciences Authority ("HSA") had accepted the New Drug Application ("NDA") for toripalimab, both in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma ("NPC"), and as a single agent for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. Additionally, the HSA has also granted priority review designation to the NDA.

This NDA was submitted through Project Orbis, an initiative of the US Food and Drug Administration (FDA)'s Oncology Center of Excellence (OCE). Project Orbis provides a collaborative mechanism and framework between the FDA and regulatory partners in other countries and regions for concurrent submission and review of oncology drugs. At present, eight regulatory agencies have joined Project Orbis, including the FDA, the Australia Therapeutic Goods Administration ("TGA"), HSA, Health Canada (HC), the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA"), etc.

Project Orbis currently accepts applications for oncology indications. An application should generally qualify for FDA priority review, meaning that the drug is intended to treat a serious disease and, if approved, would significantly improve the safety or efficacy of the treatment and offer notable clinical benefits. Under the framework of Project Orbis, collaboration between international regulators may expedite patient access to new cancer treatments in other countries.

Toripalimab for the treatment of NPC meets these application requirements and is the first Chinese oncology drug to be included in Project Orbis. Previously, two NDAs for toripalimab for the treatment of NPC had been submitted to the TGA through Project Orbis and were successfully accepted. Junshi Biosciences will explore accelerated marketing opportunities in countries and regions where it is applicable.

The NDA is supported by results from JUPITER-02, a randomized, double-blind, placebo-controlled, multinational multi-center Phase 3 clinical study (NCT03581786), for the first-line treatment of NPC, as well as results from POLARIS-02, a multi-center, open-label, pivotal Phase 2 clinical study (NCT02915432), for second-line or later treatments for recurrent or metastatic NPC.

Results from JUPITER-02, the first international, multi-center, double-blind, randomized, placebo-controlled Phase 3 clinical study using immunotherapy for the treatment of NPC with the largest sample size, were presented at the plenary session of the 2021 American Society of Clinical Oncology (ASCO) annual meeting (#LBA2), and published in *Nature Medicine* and the *Journal of the American Medical Association* (*JAMA*). The study found that compared to chemotherapy alone, toripalimab in combination with chemotherapy for the first-line treatment of metastatic or recurrent NPC significantly improved progression-free survival (PFS) and overall survival (OS), with a median PFS of 21.4 months, and a 3-year OS rate of 64.5%; it also reduced the risk of disease progression or death by 48% and the risk of death by 37%, all while demonstrating a manageable safety profile.

The POLARIS-02 results were published online in January 2021 in the *Journal of Clinical Oncology*. These findings showed that toripalimab demonstrated durable antitumor activity in patients with recurrent or metastatic NPC who failed previous chemotherapy, with an objective response rate (ORR) of 20.5%, a median duration of response (DoR) of 12.8 months, and a median OS of 17.4 months while maintaining a manageable safety profile.

So far, toripalimab has been approved for 7 indications in China, with 3 supplementary new drug applications (sNDA) currently under regulatory review. Internationally, it has been approved for 2 NPC indications in the US, and marketing approval applications are currently under regulatory review in the European Union, UK, Australia and Singapore.

About NPC

NPC is a malignant tumor that occurs in the nasopharyngeal mucosal epithelium and is one of the most common types of head and neck cancer. According to the World Health Organization, the number of newly diagnosed NPC cases in 2020 exceeded 130,000 worldwide. Due to the location of the primary tumor, surgery is rarely an option, while radiotherapy alone or in combination with chemotherapy are the main treatment options for localized cancers.

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. 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 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.

In Singapore, the NDA application was accepted by the HSA in January 2024.

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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