Junshi Biosciences Announces New Chemical Entity Application for Toripalimab Accepted by Australia's TGA

SHANGHAI, China, December 1, 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 Therapeutic Goods Administration of the Australian Government Department of Health and Aged Care (TGA) has accepted the New Chemical Entity (NCE) application for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma (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. Additionally, the TGA has also granted an orphan drug designation to toripalimab for the treatment of NPC.

This NCE application was submitted through Project Orbis, an initiative of the FDA's Oncology Center of Excellence (OCE) that provides a collaborative mechanism and framework among the FDA and regulatory partners in other countries and regions, for concurrent submission and review of oncology drugs. At present, seven other regulatory agencies have joined Project Orbis, including the TGA, Singapore Health Sciences Authority (HSA), Health Canada (HC), MHRA, etc.

Project Orbis currently accepts applications for oncology indications. An application should generally qualify for FDA priority review, meaning that the drug must be intended to treat a serious disease and, if approved, would significantly improve the safety or efficacy of the treatment; furthermore, the drug should have a high impact and significant clinical benefits. Under the framework of Project Orbis, collaboration among international regulators may allow patients with cancer to receive earlier access to new treatments in other countries.

Toripalimab for the treatment of NPC meets these application requirements and is the first domestic oncology drug to be included in Project Orbis. Junshi Biosciences will explore the possibility of fast marketing in these countries and regions where the pathway is applicable.

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.

This NCE application is supported by results from JUPITER-02, a randomized, double-blind, placebo-controlled, multinational multi-center Phase III clinical study (NCT03581786), for the first-line treatment of NPC and the results from POLARIS-02, a multi-center, open-label, pivotal Phase II clinical study (NCT02915432), for second-line or more prior treatments for recurrent or metastatic NPC.

The results of JUPITER-02, the first multinational multi-center, double-blind, randomized, placebo-controlled Phase III clinical study with immuno-oncology therapy for the treatment of NPC with the largest sample size, were published at the plenary session of the 2021 American Society of Clinical Oncology (ASCO) annual meeting (#LBA2), and in *Nature Medicine* and the *Journal of the American*

Medical Association (*JAMA*). The results showed 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), reduced the risk of disease progression or death by 48% and the risk of death by 37%, and demonstrated a manageable safety profile.

The POLARIS-02 results were published online in January 2021 in the *Journal of Clinical Oncology*. The results 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 with a manageable safety profile.

So far, toripalimab has been approved for 6 indications in China, with 4 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 for 2 indications in NPC and esophageal carcinoma are currently under regulatory review in the European Union and UK.

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 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, an NCE was accepted by the 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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