Junshi Biosciences Announces Toripalimab's Approval in Singapore

SHANGHAI, China, March 26, 2025 -- 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 New Drug Application (the "NDA") for toripalimab (Singapore trade name: LOQTORZI®) in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma ("NPC") has been approved by the Singapore Health Sciences Authority (the HSA). Toripalimab has become the first and only approved immuno-oncology treatment for NPC in Singapore.

NPC is a malignant tumor that occurs in the epithelium mucosae of the nasopharynx and is one of the most common types of head and neck cancers. According to GLOBOCAN 2022 statistics, the number of newly diagnosed NPC cases in 2022 exceeded 120,000 worldwide. Toripalimab is the only preferred regimen recommended for the comprehensive treatment of recurrent or metastatic NPC in the National Comprehensive Cancer Network (NCCN) Guidelines (Version 1.2025) for head and neck cancers.

The approval is primarily based on the results from JUPITER-02 (NCT03581786), the first international multi-center, double-blind, randomized Phase 3 clinical study in NPC immunotherapy with the largest sample size. JUPITER-02 is also the world's first Phase 3 clinical study with preset statistical verification (Type I error control) demonstrating a significant overall survival ("OS") benefit for first-line immunotherapy combined with chemotherapy compared to chemotherapy alone in NPC. JUPITER-02's results were presented in an oral report during a Plenary Session at the 2021 American Society of Clinical Oncology (ASCO) annual meeting (#LBA2). These results were subsequently featured on the cover of Nature Medicine and published in full in the Journal of the American Medical Association (JAMA). The results of the study showed that, compared to chemotherapy alone, toripalimab in combination with chemotherapy reduced the risk of disease progression by 48% and the risk of death by 37%. The median progression-free survival ("PFS") in the toripalimab plus chemotherapy group was prolonged by 13.2 months compared to chemotherapy alone, from 8.2 months to 21.4 months. In addition, patients treated with this combined therapy achieved a higher objective response rate ("ORR") and longer duration of response ("DoR"), with a complete response (CR) rate of 26.7%, and no new safety signal was identified. Long-term survival follow-up data was presented at ASCO 2024, with a 5-year survival rate of 52%.

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, said, "Toripalimab's approval in Singapore represents our formal entry into the Southeast Asian market. Southeast Asia is a region with a high incidence of NPC, and we are proud to introduce this groundbreaking therapy to address unmet medical needs and transform the local treatment landscape. As of now, toripalimab has received marketing authorization in over 35 countries and regions across four continents. We remain committed to our 'In China, For Global' strategy, advancing innovative medicines from China to improve healthcare for patients across the globe."

The NDA was submitted under Project Orbis. Project Orbis, initiated and advocated by the Oncology Center of Excellence (OCE) of the U.S. Food and Drug Administration (the "FDA"), provides a collaborative mechanism and framework among the FDA and regulatory authorities in other countries and regions, allowing different regulatory authorities to jointly review the applications for registration of oncology

drugs. Toripalimab was the first domestic oncology drug to be included in Project Orbis. Previously, the Therapeutic Goods Administration of the Australian Government Department of Health and Aged Care (the "TGA") approved two New Chemical Entity applications for toripalimab in NPC under Project Orbis.

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 to induce PD-1 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, Europe and Southeast Asia. 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 the Chinese mainland, toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing (approved in China as TUOYI®). Currently, there are eleven approved indications for toripalimab in the Chinese mainland:

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;
8. in combination with axitinib for the first-line treatment of patients with medium to high risk unresectable or metastatic renal cell carcinoma (RCC);

9. in combination with etoposide plus platinum for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC);
10. in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic triple-negative breast cancer (TNBC);
11. in combination with bevacizumab for the first-line treatment of unresectable or metastatic hepatocellular carcinoma (HCC) patients.

The first 10 indications have been included in the National Reimbursement Drug List (NRDL) (2024 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma, perioperative treatment of NSCLC, treatment of RCC and treatment of TNBC. In October 2024, toripalimab for the treatment of recurrent or metastatic NPC was approved in Hong Kong SAR, China.

Internationally, toripalimab has been approved for marketing in the United States, the European Union, India, the UK, Jordan, Australia, Singapore and other countries and regions. In addition, toripalimab BLAs are under reviews in many countries or regions around the global.

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. Five of the company's products have received approvals in China and international markets, one of which is toripalimab, China's first domestically produced and independently developed anti-PD-1 monoclonal antibody. Toripalimab has been approved in over 35 countries and regions including China, the US, and Europe. 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 2,500 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc.). For more information, please visit: http://www.junshipharma.com.

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