Junshi Biosciences Announces Toripalimab Obtained Approval for Marketing in India and China's Hong Kong SAR

SHANGHAI, China, October 15, 2024 -- 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, and its wholly-owned subsidiary, TopAlliance Biosciences Inc. (TopAlliance Biosciences), announce that toripalimab (Indian trade name: ZYTORVI®, Hong Kong trade name: LOQTORZI®) has been approved for marketing in India and China's Hong Kong Special Administrative Region ("SAR"), for treatment of recurrent or metastatic nasopharyngeal carcinoma ("NPC"). The approved indications are: 1) toripalimab in combination with cisplatin and gemcitabine, for first line treatment of adults with metastatic or with recurrent, locally advanced NPC; 2) toripalimab as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy. Zytorvi® shall be imported and commercialized in India by Dr. Reddy's Laboratories Ltd.

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, said, "As of now, toripalimab has been approved for marketing in over 30 countries and regions across three continents worldwide. With its differentiated clinical layout and outstanding clinical performance, it has brought a new treatment that can change the therapeutic landscape to local doctors and patients, which we are very excited about. Moving forward, we will continue to implement the company's international strategy of 'In China, For Global' and work with partners to provide more overseas patients with high-quality innovative drugs from China."

NPC is a malignant tumor that occurs in the epithelium of the nasopharynx. According to GLOBOCAN 2022 statistics, the number of newly diagnosed NPC cases in 2022 exceeded 120,000 worldwide. Due to the location of the primary tumor, surgery is rarely an option. Toripalimab is the first and only treatment for NPC approved in India and China's Hong Kong SAR.

The marketing approvals are supported by results from JUPITER-02, a randomized, double-blind, placebo-controlled, multinational multi-center Phase 3 clinical study (NCT03581786) that examined toripalimab in combination with gemcitabine-cisplatin as the first-line treatment of NPC, as well as results from POLARIS-02, a multi-center, open-label, pivotal Phase 2 clinical study (NCT02915432) that evaluated toripalimab as the second-line or later treatment for recurrent or metastatic NPC.

The JUPITER-02 study is the first international multi-center, double-blind, randomized Phase III clinical study in the field of immunotherapy for NPC with the largest sample size, and the world's first Phase III clinical study with preset statistical verification (Type I error control) for Overall Survival ("OS") for first-line immunotherapy combined with chemotherapy for NPC compared to chemotherapy alone and demonstrated a survival benefit. The study results were presented in an oral report during the Plenary Session of the 2021 annual meeting of the American Society of Clinical Oncology (ASCO) (#LBA2) and were subsequently featured on the cover of *Nature Medicine*. The results were also published in full in the *Journal of the American Medical Association (JAMA)*. The results 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), longer duration of response (DoR), and no new safety signal was identified. Long-term survival follow-up data, presented at ASCO 2024, reported a 5-year survival rate of 52.0% in the toripalimab treated arm.

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 ORR of 20.5%, a 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 marketing in over 30 countries and regions, including the Chinese mainland, Hong Kong SAR, the US, European Union, and India. Several marketing applications are currently under regulatory review or submitted for review in UK, Australia, Singapore, Malaysia, South Africa, Chile, Jordan, Brazil, Columbia, Philippines, Thailand and Indonesia.

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 the Chinese mainland, toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing (approved in China as TUOYI®). Currently, there are ten 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).

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 US 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, the European Committee approved marketing authorization applications (MAA) for toripalimab 1) combined with cisplatin and gemcitabine for the first-line treatment of patients with locally recurrent or metastatic NPC and 2) combined with paclitaxel and cisplatin for the first-line treatment of patients with unresectable locally advanced/recurrent or metastatic ESCC in September 2024. The UK Medicines and Healthcare products Regulatory Agency (MHRA) accepted the MAA in 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 Asia, toripalimab obtained import license from the National Regulatory Authority (NRA) of India in September 2024, and marketing approval from Pharmacy and Poisons Board of China's Hong Kong SAR in October 2024, for the treatment of recurrent or metastatic NPC. In Singapore, the new drug

application (“NDA”) application was accepted by the Singapore Health Sciences Authority (HSA) in January 2024. The HSA has also granted priority review designation for the NDA.

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 over 30 countries and regions including China, the US, the European Union, etc. 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 2,500 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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