# Junshi Biosciences Announces European Commission Approval for Marketing of Toripalimab

SHANGHAI, China, September 24, 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 the European Commission (EC) has approved toripalimab (European trade name: LOQTORZI®) for the treatment of two indications:

- Toripalimab 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);
- Toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma (ESCC).

In July, a positive opinion was issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the marketing authorization application (MAA) of these two indications. This approval applies to all 27 member states of the European Union, Iceland, Norway and Liechtenstein, making toripalimab the first and only drug in Europe for the treatment of NPC and the only first-line treatment for advanced or metastatic ESCC, regardless of PD-L1 status.

NPC is a malignant tumor that occurs in the nasopharyngeal mucosal epithelium and is one of the most common types of head and neck cancers globally. 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. The latest European Society of Medical Oncology (ESMO) Guidelines recommend immunotherapy combined with chemotherapy as the first-line treatment for recurrent or metastatic NPC.

The approval of the NPC indication is primarily based on the results from the JUPITER-02 study (a randomized, double-blind, placebo-controlled, multinational multi-center Phase III clinical study, NCT03581786). 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 higher disease control rate (DCR), 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%.

EC is one of the most common malignant tumors in the alimentary tract. According to GLOBOCAN 2022

statistics, esophageal cancer is the 11th most commonly diagnosed cancer and the seventh leading cause of cancer death worldwide, with over 511,000 new cases and over 445,000 deaths in 2022. ESCC and esophageal adenocarcinoma are the two main histological subtypes of esophageal cancer. The ESMO Guidelines recommend PD-1 blocking antibodies combined with chemotherapy for the treatment of patients with advanced or metastatic ESCC with PD-L1 positive status.

The approval of the ESCC indication is primarily based on the results from the JUPITER-06 study (a randomized, double-blind, placebo-controlled, multi-center Phase III clinical study, NCT03829969). The study aimed to evaluate the efficacy and safety of toripalimab in combination with paclitaxel/cisplatin (TP) for the first-line treatment of advanced ESCC compared with placebo in combination with chemotherapy. The results were first presented in an oral session during the ESMO Congress 2021 and later published in *Cancer Cell* and *Journal of Clinical Oncology*, two leading international oncology journals. The results of the study showed that toripalimab in combination with chemotherapy resulted in superior PFS and OS in patients with advanced or metastatic ESCC, the median OS was prolonged by 6 months to 17 months and the risk of disease progression or death in patients was significantly reduced by 42%. Futhermore, there was significant improvement in survival benefits regardless of PD-L1 status.

Professor Ruihua XU, Principal Investigator and President of Sun Yat-sen University Cancer Center, said, “Both NPC and EC are highly prevalent in Asia, while the development of innovative therapies for these cancer types has been slow in Europe and the Americas. The outstanding results from the JUPITER-02 and JUPITER-06 studies reflect the pioneering leadership of Chinese researchers in the diagnosis, treatment, and clinical research of NPC and EC. We hope that this ‘Chinese Solution’ will truly transform the outlook for patients around the world who have long lacked effective treatment options for these cancers, and bring them renewed hope for survival!”

Dr. Jianjun ZOU, General Manager and CEO of Junshi Biosciences, said, “‘In China, For Global’ has been a core strategic goal of Junshi Biosciences since its inception. The approval of toripalimab by the EC signifies that, following our success in China and the US, our global commercial strategy has officially expanded into Europe. It also reflects the international recognition of our research and production quality for innovative drugs. Moving forward, we will continue to collaborate with our partners on the commercialization of toripalimab in Europe, and provide high-quality, innovative therapies from China to more patients worldwide.”

Dr. Patricia Keegan, Chief Medical Officer of TopAlliance Biosciences, said, “Junshi Biosciences and TopAlliance Biosciences are dedicated to producing innovative therapies that offer survival benefits to patients around the world while consistently addressing the clinical needs of local populations. This approval represents another significant milestone in our entry into the global market. In addition to toripalimab, we have several promising indications and drugs under development internationally. We believe that our commitment to providing patients with more effective treatment options will continually motivate us toward becoming a leading international innovative enterprise.”

**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 April 2024, the Drug Office at the Department of Health in the Government of the Hong Kong Special Administration Region (DO) accepted the NDA 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 the United States, the US 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, the EC 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 Singapore, the 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 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 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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