Junshi Biosciences Announces Toripalimab's Approval in Australia

SHANGHAI, China, January 17, 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, and its wholly-owned subsidiary, TopAlliance Biosciences Inc. (TopAlliance Biosciences), announced that toripalimab, the anti-PD-1 monoclonal antibody self-developed by the company, has obtained the marketing authorization issued by the Therapeutic Goods Administration of the Australian Government Department of Health and Aged Care (the "TGA"). The New Chemical Entity (the "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 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 has been approved by TGA. Toripalimab has become the first and only immuno-onocology treatment for NPC in Australia.

This NCE application was submitted under Project Orbis. Project Orbis, initiated and advocated by the Oncology Center of Excellence (OCE) of the US 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 included in Project Orbis. Additionally, the TGA also granted an orphan drug designation to toripalimab for the treatment of NPC, which has accelerated the review and registration process to a certain extent.

General Manager and CEO of Junshi Biosciences, Dr. Jianjun ZOU, said, "Toripalimab has made significant strides in its internationalization. As of today, toripalimab has been approved in 35 countries across four continents and offers hope to patients worldwide. This recent approval in Australia is not only extremely meaningful to the nasopharyngeal carcinoma patients there, but it also represents our company's continued efforts toward globalization. In the following days, we will closely collaborate with our partner Dr. Reddy's Laboratory to expedite toripalimab's availability in Australia, ensuring that local patients can benefit from this treatment as soon as possible."

M.V. Ramana, CEO of Branded Markets, Dr. Reddy's, said: "This approval is a significant milestone in our collaborative efforts with Junshi Biosciences to make their novel treatment available to patients around the world. Toripalimab is the first and only immuno-onocology treatment for nasopharyngeal carcinoma in Australia, and meets a significant unmet need for patients. In oncology, our offerings aim to build an end-to-end ecosystem of care – access to current standard of care cancer medicines across multiple countries globally, innovation in formulations, strategic collaborations for novel innovative molecules, beyond-the-pill support such as nutrition and digital tools. Following our successful launch of toripalimab in India, we are looking forward to bringing it to patients in Australia and other markets in the coming days."

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 of the NPC indications is primarily based on the results from JUPITER-02 (a randomized, double-blind, placebo-controlled, multinational multi-center Phase 3 clinical study for the first-line treatment of NPC, NCT03581786), and the results from POLARIS-02 (a multi-center, open-label, pivotal Phase 2 clinical study for second-line or later treatment of recurrent or metastatic NPC, NCT02915432).

The JUPITER-02 study is the first international multi-center, double-blind, randomized Phase 3 clinical study in NPC immunotherapy with the largest sample size, and is the world's first Phase 3 clinical study in which there is preset statistical verification (Type I error control) for Overall Survival ("OS") in first-line immunotherapy combined with chemotherapy for NPC compared to chemotherapy alone that demonstrated a survival benefit. The results of the study 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 (IF: 58.7). The results were also published in full in the Journal of the American Medical Association (JAMA, IF: 63.1). 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 in combination with 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%.

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 and a manageable safety profile in patients with recurrent or metastatic NPC who had failed prior chemotherapy, with an ORR of 20.5%, a DoR of 12.8 months, and a median OS of 17.4 months.

As of today, toripalimab has been approved for marketing in over 35 countries and regions in 4 continents, including China, Hong Kong SAR, the United States, the European Union, the UK, Australia, India, Jordan, etc.

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 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 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 and other countries and regions. In addition, toripalimab BLAs are under reviews in many countries around the global, including the Singapore Health Sciences Authority (HSA).

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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