Junshi Biosciences Announces Commercialization Partnership with LEO Pharma for Toripalimab in Europe

SHANGHAI, China, January 20, 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 a distribution and marketing partnership with LEO Pharma for toripalimab in Europe. This collaboration aims to promote the accessibility of toripalimab in Europe, offering high-quality, innovative treatments to patients across up to 32 European countries.

Toripalimab, independently developed by Junshi Biosciences, is a monoclonal antibody targeting PD-1 for the treatment of multiple malignant tumors. To date, toripalimab has been approved for marketing in over 35 countries and regions around the world. In 2024, toripalimab received approvals from both the European Commission (EC) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for the following indications: 1) 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); 2) in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC). Toripalimab is 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 tumor PD-L1 expression status.

Under the agreement, LEO Pharma will be responsible for toripalimab's distribution, promotion, sales, etc., in up to 32 countries, including all member states of the European Union (EU) and the European Economic Area (EEA), as well as Switzerland and the United Kingdom. TopAlliance Biosciences Europe will remain the Marketing Authorization Holder (MAH) for toripalimab in Europe, retaining responsibility for product development, manufacturing, registration, pharmacovigilance, quality management, etc. LEO Pharma will make payments, including an upfront payment, milestone payments if LEO Pharma wishes to pursue any subsequently approved indications, and a revenue share of a double-digit percentage on the net sales of toripalimab throughout the collaboration territory.

Dr. Sheng YAO, Senior Vice President of Junshi Biosciences and CEO of TopAlliance Biosciences, said, "The partnership with LEO Pharma has established a significant milestone for Junshi Biosciences in the European market and is closely aligned with the company's global expansion strategy. Europe has been identified as a pivotal strategic region for the corporate business growth. As the Marketing Authorization Holder (MAH) of the product in Europe, the company has already established a local operational center and is actively collaborating with local health authorities to prepare for the successful commercial launch of toripalimab in Europe. As a century-old multinational pharmaceutical company headquartered in Europe, LEO Pharma has established a mature distribution network and rich marketing expertise in the local markets. By leveraging both parties' strengths in R&D, manufacturing, and commercialization, we believe toripalimab will be efficiently integrated into the Europe markets benefitting local patients-in-need. Moving forward, we will continue to implement our 'In China, For Global' strategy and work with partners to provide high-quality, innovative therapies from China to patients worldwide."

Jean Monin, Executive Vice President of Thrombosis Business Unit, LEO Pharma, commented, "We are excited to partner with Junshi Biosciences, supplementing LEO Pharma's Thrombosis business, which already serves patients with cancer-associated thrombosis. The distribution and marketing partnership

for LOQTORZI® brings an important new treatment option to areas of high unmet medical need and focuses on a specialty hospital product that complement our existing heparin-based anti-coagulation treatments for cancer-associated thrombosis and other specialty patients. Leveraging our commercial platform, LOQTORZI® will create valuable synergies and drive continued growth."

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 ten 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 LEO Pharma

LEO Pharma is a global company dedicated to advancing the standard of care through innovation for the benefit of people with skin conditions. LEO Pharma also provides anti-coagulant therapy for cancer patients and other specialty patients. LEO Pharma is co-owned by majority shareholder the LEO Foundation and, since 2021, Nordic Capital. LEO Pharma offers a broad portfolio of treatments, serving 100 million patients annually. Headquartered in Denmark, LEO Pharma has a global team of 4,000 people. In 2023, the company generated net sales of $1.6 billion. For more information, please visit: https://www.leo-pharma.com.

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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