Junshi Biosciences Announces Four New Indications of Toripalimab Included in the NRDL

SHANGHAI, China, November 28, 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, announced that four new indications of the company's product toripalimab injection (trade name: TUOYI®, product code: JS001) were successfully included in Category of the National Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (Year 2024) (the "NRDL"). The new edition of the NRDL will be officially come into effect on 1 January 2025.

Up till now, ten approved indications of TUOYI® in Chinese mainland were all included in the NRDL and it is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma, perioperative treatment of non-small cell lung cancer ("NSCLC"), treatment of renal carcinoma and treatment of triple-negative breast cancer ("TNBC").

Indications:

1. Treatment for unresectable or metastatic melanoma after failure of standard systemic therapy;

2. Treatment for locally advanced or metastatic urothelial carcinoma that failed platinum containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum containing chemotherapy;

3. Treatment for patients with recurrent/metastatic nasopharyngeal carcinoma ("NPC") after failure of at least two lines of prior systemic therapy;

4. First-line treatment for patients with locally recurrent or metastatic NPC;

5. First-line treatment for patients with unresectable locally advanced/recurrent or metastatic esophageal squamous cell carcinoma;

6. First-line treatment for patients with EGFR mutation-negative and ALK mutation-negative, unresectable, locally advanced or metastatic non-squamous NSCLC;

7. The product in combination with chemotherapy as perioperative treatment and subsequently, monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage IIIA-IIIB NSCLC;

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

9. The product in combination with etoposidein plus platinum for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC);

10. The product in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic TNBC with a well-validated test to evaluate PD-L1 positive (CPS ≥ 1).

Items 7 to 10 are new indications included in the NRDL.

In addition, the successful inclusion of the 4 new indications of TUOYI® in the NRDL is the first time that the NRDL included immunotherapy for perioperative NSCLC, renal carcinoma, small cell lung cancer and TNBC.

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).

All of 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, renal carcinoma and TNBC, and perioperative treatment of NSCLC. In October 2024, toripalimab for the treatment of recurrent or metastatic NPC was approved in Hong Kong SAR, China.

In terms of international layout, toripalimab has been approved for marketing in the United States, the European Union, India, the UK, Jordan and other countries and regions. In addition, the Australia Therapeutic Goods Administration (TGA) and the Singapore Health Sciences Authority (HSA) accepted the new chemical entity application and the new drug 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, respectively.

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 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 35 countries and regions including China, the US, and Europe. 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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