Junshi Biosciences Announces Submission of a Marketing Authorization Application for Toripalimab to the UK Medicines and Healthcare Products Regulatory Agency

-- 2nd MAA submission in Europe reflects toripalimab's steady yet speedy progress towards global commercialization

SHANGHAI, China, November 24, 2022 (GLOBE NEWSWIRE) – 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 today that the company has submitted a marketing authorization application ("MAA") to the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA") for toripalimab. The indications requested in the MAA are: 1) Toripalimab, in combination with cisplatin and gemcitabine, for the first-line treatment of patients with locally recurrent or metastatic nasopharyngeal carcinoma ("NPC") and 2)Toripalimab, in combination with paclitaxel and cisplatin, for the first-line treatment of patients with unresectable locally advanced/recurrent or metastatic esophageal squamous cell carcinoma ("ESCC"). Junshi Biosciences also submitted a MAA to the European Medicines Agency ("EMA") for toripalimab for the same indications in mid-November.

"Within a single month, we were able to submit marketing authorization applications for toripalimab to two major European regulatory agencies," said Dr. Patricia Keegan, Chief Medical Officer of Junshi/TopAlliance Biosciences. "This is emblematic of our determination and corporate efficiency in bringing innovative drugs to patients worldwide. In the coming days, we will work closely with the MHRA to promote the clinical development and application of emerging therapies in the UK."

The MAA submission for NPC and ESCC is based on the results from JUPITER-02 (an international randomized, placebo-controlled, double-blinded Phase III trial, NCT03581786) and JUPITER-06 (a randomized, placebo-controlled, double-blinded, multi-center Phase III trial, NCT03829969).

The JUPITER-02 results were first presented in the plenary session of the American Society of Clinical Oncology ("ASCO") 2021 annual meeting (#LBA2) and subsequently published in detail as the cover article of the September 2021 issue of *Nature Medicine*. According to its final progression-free survival (PFS) analysis, the toripalimab plus chemotherapy arm had a significantly longer PFS than the placebo plus chemotherapy arm as assessed by a blinded independent radiology committee (BIRC) with median PFS of 21.4 vs. 8.2 months, hazard ratio (HR)=0.52 (95% CI: 0.37-0.73), two-sided $p<0.0001$.

In 2021, two indications for the treatment of NPC were approved by the China National Medical Products Administration ("NMPA"), thereby making toripalimab the world's first immune checkpoint inhibitor approved for the treatment of NPC. In the the United States, the NPC indications of toripalimab

have been granted 2 Breathrough Therapy Designations and 1 Orphan Drug Designaion by the Food and Drug Administration ("FDA"), while the Biologics License Application ("BLA") for toripalimab for the treatment of NPC is under review. If approved, toripalimab will be the first and only drug approved for the treatment of NPC in the U.S. In Europe, toripalimab was designated as an orphan medicinal product by the European Commission ("EC") for the treatment of NPC.

The JUPITER-06 results were first presented in a mini-oral session during the 2021 European Society for Medical Oncology ("ESMO") Congress and later published in *Cancer Cell* with an editorial preview. The overall survival (OS) and PFS were significantly better in the toripalimab plus chemotherapy arm than in the placebo plus chemotherapy arm, with a median OS of 17 vs. 11 months (HR=0.58, 95% CI: 0.43-0.78, P=0.0004) and PFS HR=0.58 (95% CI: 0.46-0.74), p<0.0001.

In May 2022, the supplemental new drug application ("sNDA") for toripalimab in combination with paclitaxel and cisplatin for the first-line treatment of patients with unresectable locally advanced/recurrent or distant metastatic ESCC was approved by the NMPA in China. Additionally, US FDA has also granted an orphan drug designation to toripalimab for the treatment of patients with ESCC.

About Nasopharyngeal Carcinoma

NPC is a malignant tumor that occurs in the nasopharyngeal mucosal epithelium and is one of the most common head and neck cancers in China. According to the World Health Organization, the number of newly diagnosed NPC cases in 2020 has exceeded 130,000 worldwide. Due to the location of the primary tumor, surgery is rarely an option, and patients with localized disease are treated primarily with chemotherapy and radiotherapy. In the United States and Europe, there are presently no drugs approved for the treatment of NPC, for which recommendations for initial treatment (gemcitabine and cisplatin) are based on randomized trials conducted in China.

About Esophageal Cancer

Esophageal cancer is one of the most common malignant tumors in alimentary tract. According to data released by GLOBOCAN 2020, 604,100 new esophageal cancer cases and 544,076 deaths due to esophageal cancer occurred globally. The incidence and death rates of esophageal cancer ranked seventh and sixth among all malignant tumors around the world. ESCC and esophageal adenocarcinoma are the two main histological subtypes of esophageal cancer. For patients with advanced ESCC, recently updated ESMO guidelines recommend a platinum-fluoropyrimidine doublet with a PD-1 blocking antibody for treatment of locally advanced or metastatic ESCC. Of note, the indications for those PD-1 inhibitors approved in Europe are restricted to a subset of patients with ESCC. Therefore, there is an urgent unmet need for new drugs and treatments to extend the survival of patients with ESCC, particularly those with low PD-1 tumor expression.

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 thirty 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 European countries. 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 China, toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing (approved in China as TUOYI®). Currently, there are six approved indications for toripalimab in China:

1. unresectable or metastatic melanoma after failure of standard systemic therapy;
2. recurrent or metastatic 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 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").

The first three indications have been included in the National Reimbursement Drug List ("NRDL") (2021 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for treatment of melanoma and NPC.

In the United States, the FDA is reviewing the BLA resubmission for toripalimab in combination with gemcitabine and cisplatin as first-line treatment for patients with advanced recurrent or metastatic NPC and for toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy. The FDA has set a PDUFA action date for December 23, 2022. The FDA has granted Breakthrough Therapy designations for toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC as well as for toripalimab monotherapy in the second or third-line treatment of recurrent or metastatic NPC. Additionally, the FDA has granted Fast Track designation for toripalimab for the treatment of mucosal melanoma and Orphan

Drug designations for the treatment of esophageal cancer, NPC, mucosal melanoma, soft tissue sarcoma, and small cell lung cancer ("SCLC").

In Europe, toripalimab was also designated as an orphan medicinal product by the EU's European Commission for the treatment of NPC. In November 2022, MAA was submitted to the EMA and MHRA for: 1) toripalimab combined with cisplatin and gemcitabine for the first-line treatment of patients with locally recurrent or metastatic NPC and 2) toripalimab combined with paclitaxel and cisplatin for the first-line treatment of patients with unresectable locally advanced/recurrent or metastatic ESCC.

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. Junshi Biosciences was the first Chinese pharmaceutical company that obtained marketing approval for anti-PD-1 monoclonal antibody in China. Its first-in-human anti-BTLA monoclonal antibody for the treatment of various cancers was the first in the world to be approved for clinical trials by the FDA and NMPA and has since entered Phase Ib/II trials in both China and the US. Its anti-PCSK9 monoclonal antibody was the first in China to be approved for clinical trials by the NMPA.

In the face of the pandemic, Junshi Biosciences' response was strong and immediate, joining forces with Chinese and international scientific research institutions and enterprises to develop an arsenal of drug candidates to combat COVID-19, taking the initiative to shoulder the social responsibility of Chinese pharmaceutical companies by prioritizing and accelerating COVID-19 R&D. Among the many drug candidates is JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 and the result of the combined efforts of Junshi Biosciences, the Institute of Microbiology of the Chinese Academy of Science and Lilly. JS016 administered with bamlanivimab has been granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. Meanwhile, VV116, a new oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, is in global Phase III clinical trials. The JS016 and VV116 programs are a part of the company's continuous innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has more than 3,100 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing and Guangzhou). For more information, please visit: http://junshipharma.com.

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