# Junshi Biosciences Announces Primary Endpoint Met In Phase 3 Study of Toripalimab for 1st-line Treatment of Unresectable or Metastatic Melanoma

SHANGHAI, China, September 25, 2023 (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 that the primary endpoint—progression-free survival ("PFS" determined through independent radiological review)—of a randomized, controlled, multi-center phase III clinical study (the "MELATORCH study," NCT03430297) has met the pre-defined efficacy boundary. MELATORCH compares the company's product, toripalimab, with dacarbazine for the first-line treatment of unresectable or metastatic melanoma. Junshi Biosciences intends to submit a supplemental new drug application for this indication to regulatory authorities in the near future.

Melanoma is the most malignant type of skin cancer. According to data released by GLOBOCAN 2020, in 2020, approximately 325,000 new melanoma cases and 57,000 melanoma-related deaths were recorded globally. Though melanoma is relatively uncommon in China, its mortality rate is high (5,000 deaths amongst the approximately 16,000 new cases reported in 2017) and its incidence rate is increasing year by year. In addition, the melanoma subtype that afflicts Caucasian patients in Europe and America is mainly skin type (accounting for approximately 90%), while that of patients in China are mainly acral and mucosal type (accounting for approximately 70% to 80%). Patients with these melanoma subtypes have very different pathogenesis, tumor behavior, treatment methods and prognosis. In recent years, immune checkpoint inhibitors have achieved great success in treating melanoma and have been approved in Europe and the United States for the treatment of advanced first-line, advanced second-line or later line melanoma, as well as the adjuvant treatment of melanoma. In China, however, anti-PD-1 monoclonal antibodies have only been approved for the second- or later line treatment of advanced melanoma, and the first-line treatment of advanced melanoma is still dominated by traditional chemotherapy and targeted therapy (applicable only to patients with a BRAF V600 mutation). Therefore, there is an urgent clinical need for first-line immunotherapy for patients with advanced melanoma in China.

The MELATORCH study is China's first pivotal registrational clinical study of PD-(L)1 inhibitor for first-line treatment of advanced melanoma that produced positive results. These results showed that compared with dacarbazine, toripalimab as the first-line treatment for unresectable or metastatic melanoma significantly prolonged the PFS of patients. Toripalimab demonstrated a safety profile consistent with its safety profiles observed in prior studies, and no new safety signals were identified. The details of this study will be presented at an upcoming international academic conference.

"Through our Phase II study, POLARIS-01, we confirmed the efficacy and safety of toripalimab as a treatment for patients with second- and later line melanoma," said MELATORCH's principal investigator, Professor Jun GUO of Peking University Cancer Hospital. "Now, with the success of the MELATORCH study, the benefits of toripalimab may reach first-line melanoma patients as well. Compared to traditional chemotherapy drugs, patients treated with toripalimab monotherapy experienced improved PFS. Patients with different melanoma subtypes were also able to benefit from the treatment, an observation consistent with the findings of POLARIS-01. We are enthusiastic about the prospect of more melanoma patients benefiting from our high-quality, innovative and domestically produced drug."

Dr. Jianjun ZOU, Global Research and Development President of Junshi Biosciences, also shares her excitement. “Thanks to our nation’s accelerated review and approval policy for new drugs, in December 2018, toripalimab received conditional approval for the second- and later line treatment of advanced melanoma, based on its Phase II clinical trial. This approval bridged the gap in domestic anti-PD-1 monoclonal antibodies and made immunotherapy more accessible and affordable for many Chinese cancer patients. 5 years later, we have continued building on our past achievements in the field of melanoma treatment, and conducted a Phase III confirmatory study that demonstrates once more the robust efficacy of toripalimab. We will maintain close communication with regulatory authorites to expedite the indication registration process and make toripalimab available for usage as soon as possible.”

**About MELATORCH**

MELATORCH is a multi-center, randomized, open-label, positive-controlled Phase III clinical study designed to evaluate the efficacy and safety of toripalimab in comparison with dacarbazine for the first-line treatment of patients with unresectable or metastatic melanoma. Eligible subjects were randomized at a 1:1 ratio to receive toripalimab or dacarbazine until disease progression or intolerable toxicity. The primary endpoint is PFS determined through independent radiological review. The secondary endpoints include investigator-assessed PFS, objective response rate (ORR) as assessed by the independent review committee (IRC) or investigators, duration of response (DOR) and disease control rate (DCR), overall survival (OS) and safety profile, etc. With Professor Jun GUO from Peking University Cancer Hospital as the principal investigator, the study was conducted across 11 participating domestic institutions and enrolled a total of 256 subjects on a randomized basis.

**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 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 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).

The first three indications have been included in the National Reimbursement Drug List (NRDL) (2022 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma.

In the United States, the Biologics License Application (BLA) for toripalimab in combination with gemcitabine/cisplatin for the first-line treatment of patients with advanced recurrent or metastatic NPC and toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy is under review by the U.S. Food and Drug Administration ("FDA"). 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, marketing authorization applications (MAA) were accepted by the European Medicines Agency (EMA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (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, in December 2022 and February 2023.

**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 China's first self-developed anti-PD-1 monoclonal antibody, toripalimab. 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 3,000 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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