Junshi Biosciences Announces FDA Approval of LOQTORZI™ (toripalimab-tpzi) in All Lines of Treatment for Recurrent or Metastatic Nasopharyngeal Carcinoma (NPC)

- *LOQTORZI is the first and only FDA-approved treatment for NPC*
- *Indicated in combination with chemotherapy for 1st line treatment and as monotherapy for patients with disease progression on or after platinum containing chemotherapy, irrespective of PD-L1 status*

SHANGHAI, China, Oct. 29, 2023 -- Shanghai Junshi Biosciences Co., Ltd. (Junshi Biosciences, HKEX: 1877; SSE: 688180) today announced that the U.S. Food and Drug Administration (FDA) approved LOQTORZI™ (toripalimab-tpzi) in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and as monotherapy for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. The approval was based on results of the JUPITER-02 Phase 3 study and the POLARIS-02 Phase 2 study and is irrespective of a patient's PD-L1 status. LOQTORZI is a next-generation, programmed death receptor-1 (PD-1) monoclonal antibody that blocks PD-1 ligands PD-L1 and PD-L2 with high potency at a unique site on the PD-1 receptor, enabling the immune system to activate and kill the tumor.

In the JUPITER-02 Phase 3 study, LOQTORZI combined with chemotherapy significantly improved progression-free survival (PFS), reducing the risk of disease progression or death by 48% compared to chemotherapy alone. LOQTORZI also demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS), with treatment resulting in a 37% reduction in the risk of death versus chemotherapy alone.

The safety profile of LOQTORZI was consistent with the PD-1 inhibitor class. The incidence of Grade ≥3 adverse events (AEs) (89.7% vs 90.2%) and fatal AEs (3.4% vs 2.8%) was similar between the two arms. AEs leading to discontinuation of LOQTORZI versus placebo (11.6% vs 4.9%), immune-related adverse events (irAEs) (54.1% vs. 21.7%), and Grade ≥3 irAEs (9.6% vs. 1.4%) were more frequent in the LOQTORZI arm.

In the POLARIS-02 clinical study LOQTORZI demonstrated durable antitumor activity in patients with recurrent or metastatic NPC who failed previous chemotherapy, with an objective response rate (ORR) of 20.5%, a disease control rate (DCR) of 40.0%, and a median OS of 17.4 months with an acceptable safety profile.

NPC is an aggressive cancer that starts in the nasopharynx, the upper part of the throat behind the nose and near the base of skull. Due to the location of the primary tumor, surgery is rarely an option, and patients with localized disease are treated primarily with radiation and chemotherapy. LOQTORZI is the first FDA-approved agent for NPC patients.

"The impressive results from JUPITER-02 and POLARIS-02 have provided conclusive evidence that establishes toripalimab, in combination with chemotherapy or as monotherapy, as the standard therapy

for advanced NPC," said **Professor Ruihua Xu of Sun Yat-sen University Cancer Center**, the principal investigator of JUPITER-02 and POLARIS-02. "This great achievement was only made possible through the solid foundation laid by countless oncology experts over decades of in-depth research, as well as the selfless dedication of the patients and research teams involved in our toripalimab studies. We hope that this promising therapy will close the treatment gap for international NPC patients struggling to find effective therapies, bringing them renewed hope for better survival."

"We're excited to reach another significant company milestone of 'going overseas'," said **Dr. Ning LI, Chief Executive Officer of Junshi Biosciences**. "Following etesevimab, toripalimab has become Junshi Biosciences' second product to receive FDA approval for commercialization—an achievement that will further enhance the company's international presence. Currently, the establishment of toripalimab's global commercialization network is in progress, and the network aims to span over 50 countries. In accordance with the company's 'In China, For Global' strategy, we will continue working with our collaborators to promote the commercialization of toripalimab in other regions, in order to provide innovative and high-quality drugs from China to more patients overseas."

"Toripalimab's first overseas marketing approval was realized due to Junshi Biosciences' innovative drug development strategies, which focused on the clinical needs of Chinese and Asian patients, and used to bridge the global treatment gap for new, life-prolonging products to all patients with NPC outside of China" said **Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences**. "This approval marks a great beginning for Junshi Biosciences as toripalimab enters the global market. Beyond toripalimab, we have many more promising indications for toripalimab as well as additional drugs being studied in international clinical trials. We strive to meet patients' clinical needs across the globe by developing and providing new and more effective variety of treatment options. This goal provides strong motivation for our company as we become an international innovation-centric enterprise."

"LOQTORZI's first approval is a pivotal event for Coherus as an innovative oncology company. As a next generation PD-1 inhibitor it is the keystone of our I-O strategy to extend cancer patient survival as shown with the impressive results in NPC," said **Denny Lanfear, Chairman and Chief Executive Officer of Coherus**. "We are particularly excited to now turn our attention to developing LOQTORZI across multiple tumor types in combination with I-O agents that target the tumor microenvironment, such as our IL27-targeted antibody, casdozokitug, and our CCR8 inhibitor CHS-114, potentially greatly expanding the number of cancer patients achieving improved survival benefit."

About NPC

NPC is a type of aggressive cancer that starts in the nasopharynx, the upper part of the throat behind the nose and near the base of the skull. NPC is rare in the United States, with an annual incidence of fewer than one per 100,000. The five-year survival rate for all patients diagnosed with NPC is approximately 60%, however, those who are diagnosed with advanced disease have a five-year survival rate of approximately 49%.

Due to the location of the primary tumor, surgery is rarely an option, and patients with localized disease are treated primarily with radiation and chemotherapy. Patients treated with chemotherapy alone

experience poor prognosis: only 20% experience one-year PFS; up to 50% developed distant metastasis during their disease course; and low median OS of 29 months.

LOQTORZI™ is the first FDA-approved therapy for NPC and will represent a new standard of care for treating the disease when used in combination with cisplatin and gemcitabine in the first line setting or as monotherapy in the second line or greater setting.

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 U.S. Food and Drug Administration (FDA) has approved the Biologics License 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 in October 2023. The FDA has granted toripalimab 2 Breakthrough Therapy designations for the treatment of NPC, 1 Fast Track designation for the treatment of mucosal melanoma, and 5 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 toripalimab, China's first domestically produced and independently developed anti-PD-1 monoclonal antibody, approved in China and the US. 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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