Junshi Biosciences and Hikma Sign Exclusive Licensing Agreement for Cancer Treatment Drug Toripalimab for the Middle East and North Africa Region

SHANGHAI, China, December 26, 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, today announces a new exclusive licensing and commercialization agreement with Hikma Pharmaceuticals PLC (Hikma), a multinational pharmaceutical company, for toripalimab in the Middle East and North Africa (MENA). Under the terms of the agreement, Hikma is granted an exclusive license to develop and commercialize toripalimab injection in all its MENA markets. In addition, Junshi Biosciences will grant the right of first negotiation to Hikma for the future commercialization of three under development drugs in MENA.

Toripalimab is an innovative anti-PD-1 monoclonal antibody approved for marketing in China for six indications to date. Over thirty toripalimab clinical studies covering more than fifteen indications have been conducted globally, including in China, the United States, Southeast Asia, and Europe. Ongoing or completed pivotal clinical studies 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, among others.

"We believe Hikma is the ideal partner for us in the MENA region. As the third largest pharmaceutical company in MENA, with a history of more than 40 years, Hikma is well established and respected and offers deep-rooted expertise, with unparalleled local knowledge. The company has also demonstrated strong commercial capabilities, particularly in areas such as oncology and biotechnology," said Dr. Ning LI, CEO of Junshi Biosciences. "We anticipate that toripalimab could be the first marketed Chinese anti-PD-1 antibody in MENA. We look forward to working closely with Hikma to establish toripalimab's position in the MENA markets in order to provide patients with high-quality innovative care."

Commenting on this landmark agreement, Mazen Darwazeh, Hikma's Executive Vice Chairman and President of MENA, said: "Anti-PD-1s have changed the way cancer is treated over the past few years but, unfortunately, patient access to these treatments in the region has been sub-optimal. Toripalimab has a compelling clinical profile with impressive efficacy and safety data, and we are thrilled to be collaborating with Junshi Biosciences to equip doctors and patients in MENA with this innovative treatment." He added, "This agreement strengthens our biotech and oncology portfolio and enables us to increase patients' access to PD-1s, an important milestone in delivering on our purpose of putting better health, within reach, every day."

As part of this collaboration, Hikma is granted rights to commercialize any combination product that comprises any therapeutically active pharmaceutical agent co-formulated or co-packaged with toripalimab. Junshi Bioscieces futher grants Hikma the right of first negotiation to three of the company's novel oncology molecules.

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 Food and Drug Administration (FDA) is reviewing the Biologics License Application (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 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 submitted to the European Medicines Agency (EMA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) in November 2022 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, the EMA accepted the MAA.

About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P and BBB-/stable Fitch)

Hikma helps put better health within reach every day for millions of people around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,700 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.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. 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. As of December 3 2021, over 700,000 patients have been treated with bamlanivimab or bamlanivimab and etesevimab, potentially preventing more than 35,000 hospitalizations and at least 14,000 deaths. Meanwhile, VV116, a new oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, is in global Phase III clinical trials. A Phase III clinical study (NCT05341609) comparing the efficacy and safety of VV116 versus nirmatrelvir/ritonavir ("PAXLOVID") for patients with mild to moderate COVID-19 who are at high risk for progression to severe COVID-19, has reached its pre-specified primary endpoint and secondary efficacy endpoint. The study results show that compared to PAXLOVID, VV116 provided patients with a shorter median time to sustained clinical recovery, while achieving statistical superiority. 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, Guangzhou, etc). For more information, please visit: http://junshipharma.com.

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