Junshi Biosciences Announces Collaboration with Dr. Reddy's to Develop and Commercialize Toripalimab in 21 Countries

SHANGHAI, China, May 7, 2023 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd ("Junshi Biosciences", HKEX: 1877; SSE: 688180) announced a collaboration with Dr. Reddy's Laboratories Limited ("Dr. Reddy's") to develop and commercialize toripalimab, the anti-PD-1 monoclonal antibody in Latin America, India , South Africa, and at the election of Dr. Reddy's, also in Australia, New Zealand and other countries.

"We are thrilled to have established a partnership with Dr. Reddy's while toripalimab's global commercial network has been steadily expanding, reaching more than 50 countries and advancing our mission of being 'In China, For Global.'" said Dr. Ning LI, Chief Executive Officer of Junshi Biosciences. "Dr. Reddy's is a well-respected global pharmaceutical company and extends its business over nearly 70 countries worldwide, achieving impressive commerical presence across the globe. We hope that in the near future, leveraging Dr. Reddy's partnership and strong presence, our innovative medicines can accelerate access to new geographies and deliver better and more affordable treatment options to even more patients."

M.V. Ramana, CEO – Branded Markets (India & Emerging Markets), Dr. Reddy's said, "We are pleased to partner with Junshi Biosciences to take this important product to more patients. Oncology is a focus area for Dr. Reddy's. This partnership is a further step towards increasing our offerings to patients in oncology as we aim to build a robust and comprehensive portfolio in the segment. We are committed to facilitating access to innovative products as we pursue our goal of serving over 1.5 billion patients by 2030."

Under the license and commercialization agreement, Junshi Biosciences will grant a licence to Dr. Reddy's to develop and exclusively commercialize toripalimab in Brazil, Mexico, Colombia, Argentina, Peru, Chile, Panama, Uruguay, India and South Africa[1]. Dr. Reddy's may elect to expand the scope of the license to cover Australia, New Zealand and nine other countries[2].

Under the terms of the agreement, Junshi Biosciences also grants Dr. Reddy's the exclusive right of first negotiation for commercialization, in the event that Junshi Biosciences determines to grant any third party the rights to commercialize two other products as agreed in the agreement in one or more countries within the total 21 countries of Dr. Reddy's Territory[3].

[1] Collectively, "Dr. Reddy's Territory 1"
[2] Collectively, "Dr. Reddy's Territory 2"
[3] Both "Dr. Reddy's Territory 1" and "Dr. Reddy's Territory 2" are collectively known as "Dr. Reddy's Territory", totalling 21 countries.

Junshi Biosciences may receive up to an aggregate of US$728.3 million for upfront payment, potential expansion of Dr. Reddy's Territory and milestone payment, plus double-digit percentage of royalties on the net sales of products containing toripalimab.

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 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 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 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 Dr. Reddy's

Dr. Reddy's is a global pharmaceutical company headquartered in Hyderabad, India and listed on the New York Stock Exchange (stock code: RDY), the National Stock Exchange of India (stock code: DRREDDY), and the Bombay Stock Exchange (stock code: 500124). Established in 1984, Dr. Reddy's is committed to providing access to affordable and innovative medicines. Driven by its purpose of 'Good Health Can't Wait', Dr. Reddy's offers a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Dr. Reddy's major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Its major markets include – the United States, India, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, Dr. Reddy's continues to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, Dr. Reddy's released its first Sustainability Report in 2004. Its current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance. For more information, log on to: www.drreddys.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. In 2021, JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 administered with bamlanivimab, was granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. Meanwhile, VV116 (deuremidevir hydrobromide), a novel oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, has been approved for marketing in China and Uzbekistan. The JS016 and VV116 programs are a part of the company's continuous efforts towards innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has about 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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