Junshi Biosciences Announces Establishment of Joint Venture with Rxilient Biotech to Jointly Develop and Commercialize Toripalimab in Southeast Asia

-- The two parties will collaborate to develop and commercialize toripalimab in 9 Southeast Asian countries through a joint venture company, Excellmab
-- Excellmab will be responsible for the development, medical affairs, production of finished products, and commercialization of toripalimab within the cooperation territory. The profits available for distribution by Excellmab will be distributed in proportion to the respective shareholdings of the parties
-- Using the Excellmab platform, the two parties also plan to collaborate extensively to introduce more high-quality innovative drugs into Southeast Asian markets to achieve joint and long-term development
-- According to the progress of toripalimab's R&D and other projects, Junshi Biosciences may receive a milestone payment of up to approximately US$4.52 million, plus a certain percentage of royalties on net sales

SHANGHAI, China and SINGAPORE, March 28, 2023 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Rxilient Biotech announced the collaboration on the development and commercialization of the anti-PD-1 monoclonal antibody drug, toripalimab through joint venture in 9 Southeast Asian nations, including Thailand, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, and Vietnam. This collaboration is another significant milestone in toripalimab's journey abroad. So far, toripalimab has been involved in overseas business activities in over 30 countries, spanning across North America, the Middle East, North Africa and South East Asia.

"This extensive collaboration with Rxilient Biotech in Southeast Asia is a vital step for Junshi Biosciences as we strive to expand our global commercialization network," said Dr. Ning LI, CEO of Junshi Biosciences. "Southeast Asia boasts a thriving pharmaceutical innovation environment, flexible drug regulatory policies, and diversified medical security systems, so it has great potential as an emerging market for innovative drugs. The Rxilient team has a wealth of experience in drug registration and commercialization. They have a deep understanding of drug registration regulations and market resources of each and every ASEAN country, which allows them to quickly realize product value. They have also fostered collaborative relationships with Southeast Asian governments, medical institutions, researchers, and medical teams to establish a clinical research ecosystem. We're confident that through this joint venture model of collaboration, both parties will be able to harness our respective strengths in R&D and commercialization, and work together to improve the lives of Southeast Asian patients by bringing them China's innovative breakthroughs!"

"The establishment of Rxilient is an important step in its expansion plan to Southeast Asian market and its globalization for CMS. Rxilient has formed a team of talented with rich experiences in medical and pharmaceutical industries in Southeast Asia, and has engaged gradually in building product lines covering a wide range of therapeutic fields. Based in Singapore, it will radiate to Southeast Asia and thereafter the other global market, and strive to build a bridgehead for global Biotech and pharmaceutical companies in Southeast Asia. With the rapid economic development and the rise of the emerging middle class in Southeast Asia, Southeast Asia will play the role as a new engine of the growth to the world pharmaceutical and biotechnical market in the future," said Dr. LEE Ker Yin, CEO of Rxilient. "As a leading innovative pharmaceutical company in China, Junshi Biosciences developed intravenous toripalimab, the first PD-1 product independently developed and launched in China with

high competitivity. We are establishing a joint venture with great sincerity to combine the advantages of the Rxilient's drug registration and commercialization and the strong R&D capabilities of Junshi Biosciences to introduce intravenous toripalimab and may be more high-quality innovative drugs/ biological medicinal product into the Southeast Asian market with a target to meet the unmet medical needs in Southeast Asia."

Independently developed by Junshi Biosciences, toripalimab was the first Chinese anti-PD-1 monoclonal antibody that obtained marketing approval in China. Junshi Biosciences has conducted over 30 clinical trials globally (in China, the US, Southeast Asia, and Europe) covering more than 15 indications, including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney, and skin. Six of these indications have been approved in China, and multiple marketing applications are currently under review by regulatory agencies in the US, EU, and UK.

According to the terms of the agreement, Rxilient Biotech will subscribe to the newly issued shares of Excellmab for US$4,999,999, and Junshi Biosciences will pay for the subscription amount under the Shareholders Agreement by way of granting Excellmab with the relevant rights under the License Agreement. Upon completion of the issuance, Rxilient Biotech and Junshi Biosciences will own 60% and 40% of Excellmab, respectively.

Excellmab will be responsible for the development, medical affairs, production of finished products, and commercialization of relevant products within the cooperation territory. The profits available for distribution by Excellmab will be distributed in proportion to the respective shareholdings of the two parties.

Excellmab will also obtain a right of first negotiation for the commercialization of four other products under research as stipulated in the License Agreement in the cooperation territory. According to the progress of toripalimab's R&D and other projects, Junshi Biosciences may receive a milestone payment of up to approximately US$4.52 million, plus a certain percentage of royalties on net sales.

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 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").
7. 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 terms of international layout, 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). In December 2022 and February 2023, the European Medicines Agency (EMA) and the Medicines and Healthcare Products Regulatory Agency (MHRA) accepted the marketing authorization application (MAA) for toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of patients with locally recurrent or metastatic NPC, and 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, respectively.

About Rxilient Biotech and Excellmab

Rxilient Biotech, established in November 2021, is a subsidiary controlled by China Medical System Holdings Limited ("China Medical System", a company whose shares are listed on The Stock Exchange of Hong Kong Limited (stock code: 867)). Rxilient Biotech and other companies related to China Medical System that are involved in Southeast Asian businesses (together with Rxilient Biotech, "Rxilient ") form an open platform integrating innovative R&D, preparation contract development and manufacturing organization (CDMO), manufacturing, marketing and promotion. By virtue of China Medical System's capability in global investment and acquisition of high-quality for over 20 years products, excellent market commercialization experience, strong self-owned cash flow and leading venture capital and investment and financing concepts, Rxilient cooperates with the world's leading biopharmaceutical companies to introduce high-quality medicines into Southeast Asia and ultimately realize local manufacturing, explore the construction of a "bridgehead" in Southeast Asia for global pharmaceutical companies to step into the global market.

Established in February 2023, Excellmab was a wholly-owned subsidiary of Rxilient Biotech prior to the execution of the Shareholders Agreement.

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, has been approved for marketing in China and Uzbekistan. 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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