Coherus and Junshi Biosciences Share Update on the FDA Review of the Biologics License Application (BLA) for Toripalimab as Treatment for Recurrent or Metastatic Nasopharyngeal Carcinoma (NPC)

- FDA has been unable to travel to China to conduct the required site inspection resulting in delayed action on the BLA -

- Coherus and Junshi Biosciences are actively engaged in ongoing discussions with the FDA to support the inspections and gain approval of toripalimab for patients with NPC in the U.S. as quickly as possible -

SHANGHAI, China, and REDWOOD CITY, Calif., Dec. 24, 2022 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS) today announced that the companies have not received an action letter from the U.S. Food and Drug Administration (FDA, the Agency) regarding the Biologics License Application (BLA) for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma (NPC) by the Prescription Drug User Fee Action (PDUFA) date of December 23, 2022.

The FDA previously communicated that an on-site inspection of Junshi Biosciences' manufacturing facility for toripalimab is required before the Agency can approve the application; however, they were unable to conduct the inspection during the current review cycle due to the ongoing impact of COVID-19 related restrictions on travel in China. The BLA for toripalimab remains under review, and Junshi Biosciences and Coherus are engaged in ongoing discussions with the Agency about the pre-approval inspection plans.

"There is a significant unmet need for those living with NPC, and toripalimab has demonstrated significant and clinically meaningful improvement as recognized by the FDA's Breakthrough Therapy Designation. Both Coherus and the FDA are highly committed to bringing toripalimab to NPC patients in the U.S. as quickly as possible," said Theresa LaVallee, Ph.D., Coherus' Chief Development Officer. "We are working closely and collaboratively with the FDA to schedule inspections of the manufacturing facility quickly and understand the need to ensure the safety of their inspectors. We continue to support the FDA as needed to allow for their assessment of toripalimab to be finalized."

"Although toripalimab's BLA review process has been impacted by the COVID-19 pandemic, we believe the impact is temporary," said Dr. Sheng Yao, Senior Vice President of Junshi Biosciences. "Together with our partner Coherus, we are working with the FDA to expedite the facility inspection so it may be conducted safely as soon as possible in order to provide NPC patients with a treatment that has been demonstrated to be safe and effective. Our production operations are well prepared for the inspection."

The FDA has granted priority review for the toripalimab BLA for use 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. Recurrent or metastatic NPC is an aggressive head and neck tumor which has no FDA-approved treatment options.

About toripalimab

Toripalimab is an anti-PD-1 monoclonal antibody that blocks PD-L1 binding to the PD-1 receptor at a unique site that minimizes opportunities for the tumor cell to evade the immune system and decreases PD-1's expression on the T-cell as a second method of restoring the body's immune response.

The FDA granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC in 2021 as well as for toripalimab monotherapy in the second or third-line treatment of recurrent or metastatic NPC in 2020. 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").

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 an anti-PD-1 monoclonal antibody in China. Its first-in-human anti-BTLA 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.

About Coherus BioSciences

Coherus is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics.

In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. The Biologics License Application for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma is currently under review by the FDA.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, and CIMERLI™ (ranibizumab-eqrn), a biosimilar of Lucentis®, in the U.S., and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in theU.S. in 2023.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus' actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, risks and uncertainties inherent in the clinical drug development process; risks relating to the COVID-19 pandemic; risks related to our existing and potential collaboration partners; risks of the drug development position of Coherus' competitors; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review, international aspects of Coherus' business, the need to schedule inspections in China and the timing of Coherus' regulatory filings; the risk of FDA review issues; the risk of Coherus' execution of its change in strategy from a focus on biosimilars to a strategy using cash from its portfolio to fund an oncology franchise; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' drug candidates; and the risks and uncertainties of possible litigation. All forward-looking statements contained in this press release speak only as of the date of this press release. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the significant risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, see Coherus' Annual Report on Form 10-Q for the quarter-ended September 30, 2022, filed with the Securities and Exchange Commission on November 8, 2022, including the section therein captioned "Risk Factors" and in other documents that Coherus files with the Securities and Exchange Commission.

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