Coherus and Junshi Biosciences Announce PD-1 Inhibitor Toripalimab Granted Orphan Drug Designation for Small Cell Lung Cancer in the United States

REDWOOD CITY, Calif., and SHANGHAI, China, April 14, 2022 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus”, Nasdaq: CHRS) and Shanghai Junshi Biosciences Co., Ltd. (“Junshi Biosciences”, HKEX: 1877; SSE: 688180) announced today that the United States Food and Drug Administration ("FDA") has granted Orphan Drug Designation (“ODD”) for toripalimab, a PD-1 inhibitor, for the treatment of small cell lung cancer (“SCLC”). ODD is granted to drugs intended to treat rare diseases with a patient population less than 200,000 in the United States. The designation provides incentives to advance development and commercialization of drugs that have the potential to provide benefit to patients with rare diseases.

SCLC is an aggressive tumor characterized by rapid disease progression, low expression of PD-L1 and low levels of tumor infiltrating immune cells, as well as a high degree of immunosuppression. Efficacy of cancer immunotherapy has been limited in SCLC. No PD-1 inhibitors are currently approved in the United States for SCLC. Prognosis for SCLC patients is poor, with five year survival rates of approximately 20% and less than 5% for patients with extensive stage SCLC.

The JUPITER-08 study (NCT04012606) is an ongoing, randomized, double-blind, placebo-controlled, multi-center Phase 3 clinical trial evaluating PD-1 inhibitor toripalimab in combination with chemotherapy (cisplatin or carboplatin + etoposide) compared to placebo in combination with chemotherapy as the first-line treatment of extensive stage SCLC. Enrollment in this trial has been completed. The co-primary endpoints of the study are overall survival and progression free survival as assessed by the investigator.

“Toripalimab in combination with chemotherapy has demonstrated robust antitumor immunity and survival benefit in multiple tumor types including in tumors with low PD-L1 expression. This differentiated clinical activity may result from toripalimab’s unique binding epitope and internalization properties,” said Dr. Theresa LaVallee, Chief Development Officer at Coherus. “SCLC patients have a particularly poor prognosis, and new and better treatment options are clearly needed for patients with this aggressive cancer. We are pleased to be working closely with our partner, Junshi Biosciences, to evaluate toripalimab in this underserved patient population and look forward to topline data from the pivotal first line SCLC clinical trial expected later this year.”

“Lung cancer is the second most prevalent malignant tumor and has the highest mortality rate. However, there is a disparity in the development of new treatments for different subtypes of lung cancer, non-small cell lung cancer (“NSCLC”) and SCLC. For NSCLC without oncogenic mutations, multiple immuno-oncology drugs, including toripalimab, have been shown to improve survival when added to chemotherapy as compared to chemotherapy alone, whereas treatment options for SCLC patients are limited to chemotherapy with one of two PD-L1 inhibitors,” said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. “We appreciate the FDA’s recognition of our endeavors to develop new therapies for SCLC patients and, based on experience in other cancers, are hopeful that toripalimab may provide a significant advance over chemotherapy in the JUPITER-08 study.”

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 four 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.

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 melanoma and NPC.

In addition, two supplemental New Drug Applications (“NDAs”) for toripalimab are currently under review by the National Medical Products Administration (“NMPA”) in China:

- in combination with chemotherapy as the first-line treatment of patients with advanced or metastatic ESCC.
- in combination with chemotherapy as the first-line treatment of patients with advanced or metastatic NSCLC without EGFR or ALK mutations.

In the United States, the FDA has granted priority review for the toripalimab BLA for the treatment of recurrent or metastatic NPC, an aggressive head and neck tumor which has no FDA-approved immuno-oncology treatment options. The FDA has assigned a Prescription Drug User Fee Act (“PDUFA”) target action date for April 2022 for the toripalimab BLA. 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 Designation for the treatment of esophageal cancer, NPC, mucosal melanoma, soft tissue sarcoma, and SCLC. In 2021, Coherus in-licensed rights to develop and commercialize toripalimab in the United States and Canada. Coherus and Junshi Biosciences plan to file additional toripalimab BLAs with the FDA over the next three years for multiple other cancer types.

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 tumors 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 COVID-19 pandemic, Junshi Biosciences responded swiftly and strongly, 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. Meanwhile, VV116, a new oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, is in global Phase III clinical trials. 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 2,800 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing and Guangzhou). For more information, please visit: http://junshipharma.com.

About Coherus BioSciences

Coherus is a commercial stage biopharmaceutical company building a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. A biologics license application for toripalimab for the treatment of metastatic or recurrent nasopharyngeal carcinoma is currently under priority review by the FDA with a target action date of April 2022. Toripalimab is also being evaluated in pivotal clinical trials for the treatment of cancers of the lung, breast, liver, skin, kidney, stomach, esophagus, and bladder.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta® in the United States, and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) inthe United States in 2023. The FDA is currently reviewing the biologics license application for CHS-201, a biosimilar of Lucentis® (ranibizumab), with a target action date of August 2022. Coherus is also developing CHS-305, a biosimilar of Avastin® (bevacizumab).

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, including, but not limited to, statements regarding Coherus' ability to build its immuno-oncology franchise to achieve a leading market position; Coherus' ability to generate cash; Coherus' investment plans; Coherus' expectations for the launch date of YUSIMRY™ and other products; Coherus' plans to file additional BLAs for toripalimab; beliefs about toripalimab's ability to enhance treatment of patients in combination with chemotherapy; beliefs about the need for new treatment options for SCLC; and expectations for the timing of any clinical data from the Phase 3 study evaluating toripalimab for SCLC.

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, the 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 immuno-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-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on February 23, 2022, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission.

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