Junshi Biosciences and Coherus Announce Toripalimab Granted Orphan Drug Designation in the United States for Esophageal Cancer

SHANGHAI, China and REDWOOD CITY, Calif., November 15, 2021 -- Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus Biosciences, Inc. ("Coherus", Nasdaq: CHRS) announced today that the United States Food and Drug Administration ("FDA") has granted Orphan Drug Designation (ODD) for toripalimab for the treatment of esophageal cancer. Orphan drug designation is granted to drugs and biologics intended to treat rare diseases with a patient population less than 200,000 in the U.S. The designation provides incentives to advance development and commercialization of rare disease drugs.

Esophageal cancer ("EC") is a malignant tumor originating in the inner lining of the esophagus. Esophageal squamous cell carcinoma ("ESCC") and adenocarcinoma are the two main subtypes of esophageal cancer. EC is rare in the United States, with approximately 19,000 newly diagnosed cases and 15,000 deaths annually, according to estimates from the American Cancer Society. The prognosis of patients with advanced EC is poor, with five-year survival rates of less than 20%.

In September, Junshi Biosciences and Coherus announced results of the Phase 3 clinical trial, JUPITER-06, a randomized, double blind, placebo-controlled study evaluating toripalimab in combination with chemotherapy as a first-line therapy for patients with advanced or metastatic ESCC. The study met the co-primary endpoints with statistically significant and clinically meaningful improvements in progression free survival (PFS) and overall survival (OS) for patients treated with the toripalimab and chemotherapy combination, compared to chemotherapy alone. In 2022, Junshi Biosciences and Coherus are planning to submit a biologics license application ("BLA") supplement to the FDA for toripalimab in combination with platinum-based chemotherapy for the first-line treatment of advanced or metastatic ESCC. A BLA for toripalimab for advanced recurrent or metastatic nasopharyngeal carcinoma is currently under priority review by the FDA with a target action date of April 2022.

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 is thought to recharge 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, 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®). On December 17, 2018, toripalimab was granted a conditional approval by the National Medical Products Administration (NMPA) for the second-line treatment of unresectable or metastatic melanoma. In December 2020, toripalimab was successfully included in the updated National Reimbursement Drug List. In February 2021, the NMPA granted a conditional approval to toripalimab for the treatment of patients with recurrent or metastatic nasopharyngeal carcinoma ("NPC") after failure of at least two lines of prior systemic therapy. In April, the NMPA granted a conditional approval to toripalimab for the treatment of patients with locally advanced or metastatic urothelial carcinoma who failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. In addition, two supplemental NDAs, one for toripalimab in combination with chemotherapy for the first-line treatment of patients with advanced, recurrent or metastatic NPC, and the other for the first-line treatment of patients with advanced or metastatic esophageal squamous cell carcinoma, were accepted by the NMPA for review in February and July 2021, respectively.

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 currently has no FDA-approved immuno-oncology treatment options. Earlier, the FDA granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the 1st 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 designation for esophageal cancer, NPC, mucosal melanoma and soft tissue sarcoma. Earlier 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 Coherus BioSciences

Coherus is a commercial stage biopharmaceutical company with the mission to increase access to cost-effective medicines that can have a major impact on patients' lives and to deliver significant savings to the health care system. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. For additional information, please visit www.coherus.com.

Coherus markets UDENYCA® (pegfilgrastim-cbqv) in the United States and through 2023 expects to launch toripalimab, an anti-PD-1 antibody, as well as biosimilars of Lucentis®, Humira®, and Avastin®, if approved.

Avastin® and Lucentis® are registered trademarks of Genentech, Inc.

Humira® is a registered trademark of AbbVie Inc.

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 45 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 antibody for solid tumors was the first in the world to be approved for clinical trials by the FDA and NMPA and its anti-PCSK9 monoclonal antibody was the first in China to be approved for clinical trials by the NMPA. In early 2020, Junshi Biosciences joined forces with the Institute of Microbiology of Chinese Academy of Science and Eli Lilly to co-develop JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2. JS016 administered with bamlanivimab has been granted Emergency Use Authorizations (EUA) in 15 countries and regions worldwide. The JS016 program is a part of our continuous innovation for disease control and prevention of the global pandemic. Junshi Biosciences has over 2,500 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing and Guangzhou). For more information, please visit: http://junshipharma.com.

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, Coherus' ability to generate cash flow from its UDENYCA® business; Coherus' and Junshi Biosciences' ability to co-develop toripalimab, and Coherus' ability to commercialize toripalimab, or any other drug candidates developed as part of its collaboration with Junshi Biosciences in the licensed territory; Coherus' ability to expand a late-stage pipeline into the rapidly growing checkpoint inhibitor market; any market size expectation for checkpoint inhibitor therapeutic agents in the United States; the expected filing of a BLA supplement seeking approval for toripalimab for ESCC in 2022; the ability for ex-US clinical trial data from a single country to support an approval by the FDA; the potential for toripalimab to gain approval in the United States for nasopharyngeal carcinoma, esophageal squamous cell carcinoma, lung cancer, or any indication; Coherus' and Junshi Biosciences' plans to file additional toripalimab BLAs with the FDA over the next three years for other clinical indications; Coherus' plans to invest the cash generated by its biosimilar commercial business to build a focused immuno-oncology franchise; Coherus' ability to prepare for projected launches through 2023 of biosimilars of Humira®, Avastin® and Lucentis®, if approved.

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; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review and the timing of Coherus' regulatory filings; the risk of FDA review issues; 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 patent litigation. All forward-looking statements contained in this press release speak only as of the date on which they were made. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the 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, 2020, filed with the Securities and Exchange Commission on February 25, 2021,its Quarterly Report on Form 10-Q for the three and nine months ended June 30, 2021, filed with the Securities and Exchange Commission on November 8, 2021 and its future periodic reports to be filed with the Securities and Exchange Commission. Results for the quarter ended September 30, 2021 are not necessarily indicative of our operating results for any future periods.