Junshi Biosciences and Coherus Announce Toripalimab First-Line Nasopharyngeal Carcinoma Clinical Data to be Showcased in Plenary Session at 2021 ASCO Annual Meeting

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- Toripalimab data will also be featured in ASCO's official press program -

SHANGHAI, China, and REDWOOD CITY, Calif., April 29, 2021 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS), today announced that a late-breaking abstract detailing clinical data of anti-PD-1 antibody, toripalimab, in first-line treatment for recurrent or metastatic nasopharyngeal carcinoma will be featured at ASCO 2021 in the plenary session on Sunday, June 6, 2021. The abstract has also been selected for ASCO's official press program.

Details regarding the plenary session and abstract publication are as follows:

Title:	JUPITER-02: Randomized, double-blind, phase 3 study of toripalimab or placebo plus gemcitabine and cisplatin as first-line treatment for recurrent or metastatic nasopharyngeal carcinoma (NPC)
Abstract #:	LBA2
Presentation:	Plenary Session, June 6, 2021, 1:00 p.m. – 4:00 p.m. Eastern Daylight Time
Publication:	June 3, 2021, 5:00 p.m. Eastern Daylight Time

"We are excited that results of JUPITER-02, a Phase 3 clinical trial evaluating toripalimab plus chemotherapy for the first-line treatment of recurrent or metastatic nasopharyngeal carcinoma, have been selected for presentation during ASCO's plenary session, which traditionally features high-impact studies," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "Treatment of nasopharyngeal carcinoma, a specific type of head-and-neck cancer, is challenging, as the diagnosis usually occurs when the cancer is in an advanced stage and treatment options are limited."

In addition to the JUPITER-02 late-breaking abstract, ASCO accepted for publication or presentation more than two dozen additional abstracts, primarily investigator-sponsored studies, that evaluate the utility of toripalimab in a variety of cancer types including lung cancer, melanoma, urothelial carcinoma, gastroesophageal cancer, and hepatobiliary malignancies.

About Toripalimab

More than thirty company-sponsored toripalimab clinical studies covering more than fifteen indications have been conducted globally, including in China and the United States. Pivotal clinical trials are ongoing or completed evaluating the safety and efficacy of toripalimab for 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 from 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 supplemental NDA for Toripalimab in combination with chemotherapy for the first-line treatment of patients with advanced, recurrent or metastatic nasopharyngeal carcinoma was accepted by the NMPA. In the same month, 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, 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 the United States, a rolling submission of the first toripalimab Biologics License Application (BLA) is underway for the treatment of recurrent or metastatic nasopharyngeal carcinoma (NPC). The U.S. Food and Drug Administration (FDA) has granted toripalimab Breakthrough Therapy Designation for this indication. There are currently no PD-1 blocking antibodies indicated for use in NPC in the United States. Additionally, FDA has granted Fast Track status for the development of toripalimab for the treatment of mucosal melanoma and orphan drug designation for 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 rare cancers and highly prevalent cancers.

About Junshi Biosciences
Founded in December 2012, Junshi Biosciences 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 28 innovative drug candidates and 2 biosimilars, 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 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 received Emergency Use Authorization (EUA) by US FDA in Feb 2021 for the treatment of recently diagnosed, mild to moderate COVID-19 in patients who are at high risk of progressing to severe COVID-19 and/or hospitalization. The JS016 program is a part of our continuous innovation for disease control and prevention of the global pandemic. Junshi Biosciences has over 2,000 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 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.

In February 2021, Coherus and Junshi Biosciences announced a collaboration in which Coherus would in-license toripalimab, an anti-PD-1 antibody, in the United States and Canada. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. Coherus markets UDENYCA® (pegfilgrastim-cbqv) in the United States and through 2023 expects to launch biosimilars of Humira®, Avastin® and Lucentis®, if approved.

For additional information, please visit www.coherus.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 potential for toripalimab to gain approval in the United States for nasopharyngeal carcinoma or any indication; toripalimab's possibility to be the first marketed Chinese anti-PD-1 antibody in the overseas market; Coherus' and Junshi Biosciences' plans to file additional toripalimab BLAs with the FDA over the next three years for any clinical indication; 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 risk that the parties are unable to obtain clearance under the Hart-Scott Rodino Antitrust Improvements Act, from the Committee on Foreign Investment in the United States, or any other statute or regulatory agency having jurisdiction with respect to the proposed transactions, the risks and uncertainties inherent in the clinical drug development process; the risks and uncertainties of the regulatory approval process, including the timing of Coherus' regulatory filings; 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, and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the year ended December 31, 2020 are not necessarily indicative of our operating results for any future periods.

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