Coherus and Junshi Biosciences Announce Results from Phase 3 Study of Toripalimab Published in September Issue of Nature Medicine

- Toripalimab plus standard chemotherapy demonstrates improvement in PFS in first-line advanced nasopharyngeal carcinoma -

REDWOOD CITY, Calif., and SHANGHAI, China, Sept. 15, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS) and Shanghai Junshi Biosciences Co., Ltd ("Junshi Biosciences", HKEX: 1877; SSE: 688180) today announced publication of a cover article in the September issue of Nature Medicine featuring clinical data from the pivotal study "JUPITER-02", a randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating toripalimab plus chemotherapy for the first-line treatment of recurrent or metastatic nasopharyngeal carcinoma (NPC).

Titled ***Toripalimab or placebo plus chemotherapy as first-line treatment in advanced nasopharyngeal carcinoma: a multicenter randomized phase 3 trial***, the paper highlights that the addition of toripalimab to standard of care gemcitabine-cisplatin (GP) chemotherapy as a first-line treatment for patients with recurrent or metastatic NPC provided superior progression free survival (PFS) compared to GP alone [median PFS of 11.7 vs 8.0 months, hazard ratio (HR) = 0.52 (95% confidence interval (CI): 0.36–0.74), P = 0.0003], and with a manageable safety profile. The impact of the addition of toripalimab on PFS was demonstrated in patients regardless of PD-L1 expression status. Although overall survival data were not yet mature, as of February 18, 2021, a 40% reduction in risk of death was observed in the toripalimab arm compared to the placebo arm (HR = 0.603 (95% CI: 0.364–0.997)). The incidence of grade ≥3 treatment emergent adverse events (TEAEs) (89.0% vs 89.5%), TEAEs leading to discontinuation of toripalimab/placebo (7.5% vs 4.9%), and fatal TEAEs (2.7% vs 2.8%) was similar between both arms. Immune-related adverse events (irAEs) (39.7% vs. 18.9%) and Grade ≥3 irAEs (7.5% vs. 0.7%) were more frequent in the toripalimab arm. The full results can be found in the on-line edition of Nature Medicine.

"There are currently no PD-1 blocking antibodies approved for NPC in the United States. We are pleased that this study has been selected for cover article publication in this highly-respected journal," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "This is a strong signal that further validates the potential advance that toripalimab in combination with chemotherapy would represent as a new standard-of-care first-line therapy for patients with advanced NPC, an aggressive and difficult-to-treat cancer."

A biologics license application has been submitted to the U.S. Food and Drug Administration ("FDA") for toripalimab in combination with gemcitabine and cisplatin for first-line treatment for patients with advanced recurrent or metastatic NPC and toripalimab monotherapy for second-line or above treatment of recurrent or metastatic NPC after platinum-containing chemotherapy.

About JUPITER-02
The JUPITER-02 Study (ClinicalTrials.gov identifier: NCT03581786) is a randomized, double-blind, placebo-controlled, international multi-center Phase 3 clinical trial comparing the efficacy and safety of toripalimab versus placebo in combination with Gemcitabine/Cisplatin, as a first-line treatment for patients with recurrent or metastatic nasopharyngeal carcinoma. Professor Ruihua Xu from Sun Yat-sen University Cancer Centre is the lead principal investigator of the study. The largest Phase 3 clinical trial to date evaluating a checkpoint inhibitor plus chemotherapy for the first-line treatment of recurrent or metastatic nasopharyngeal carcinoma, JUPITER-02 was conducted in mainland China, Taiwan and Singapore and enrolled a total of 289 patients.

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 and the United States. Ongoing or completed pivotal clinical trials are 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 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 2021, 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 for toripalimab in combination with chemotherapy for the first-line treatment of patients with advanced, recurrent or metastatic NPC or 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 first toripalimab BLA has been submitted to the FDA for the treatment of recurrent or metastatic NPC. The FDA has granted Breakthrough Therapy designations for toripalimab in combination with chemotherapy for the 1st line treatment of recurrent or metastatic NPC and for toripalimab monotherapy in the 2nd line and subsequent treatment of recurrent or metastatic NPC. There are currently no PD-1 blocking antibodies approved for use in NPC in the United States. Additionally, FDA has granted Fast Track designation for 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 (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 44 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 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 fully human neutralizing monoclonal antibody against SARS-CoV-2. JS016 administered with bamlanivimab has been granted Emergency Use Authorizations (EUA) in more than 12 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.

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.

UDENYCA® is a trademark of Coherus BioSciences, Inc.

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

Humira® is a registered trademark of AbbVie Inc.

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; 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 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, its Quarterly Report on Form 10-Q for the three and six months ended June 30, 2021, filed with the Securities and Exchange Commission on August 5, 2021 and its future periodic reports to be filed with the Securities and Exchange Commission. Results for the quarter ended June 30, 2021 are not necessarily indicative of our operating results for any future periods.

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Source: Coherus BioSciences, Inc.