Coherus and Junshi Biosciences Announce Positive Interim Overall Survival Results of CHOICE-01, a Phase 3 Clinical Trial Evaluating Toripalimab in Combination with Chemotherapy as First-Line Treatment for Non-Small Cell Lung Cancer

- Coherus and Junshi Biosciences to meet with US FDA to discuss 1L NSCLC BLA supplement submission -

SHANGHAI, China and REDWOOD CITY, Calif., Dec. 13, 2021 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS), today announced positive results of an interim analysis of overall survival from the pivotal study "CHOICE-01" (NCT03856411), a randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating toripalimab plus standard-of-care chemotherapy as the first-line treatment of advanced squamous or non-squamous non-small cell lung cancer ("NSCLC"). This interim analysis demonstrated a statistically significant improvement in overall survival, crossing the prespecified efficacy boundary, in patients treated with toripalimab plus chemotherapy. This treatment effect was observed notwithstanding the effects of active crossover to toripalimab at disease progression for patients in the control (placebo plus chemotherapy) arm. As previously reported at the 2021 World Conference on Lung Cancer (WCLC), the study also met the primary endpoint of progression free survival (PFS) per RECIST v1.1 for the toripalimab arm as compared to chemotherapy alone.

Junshi Biosciences and Coherus plan to submit the CHOICE-01 results for publication and request a meeting with the United States Food and Drug Administration ("FDA") to discuss the submission of a Biologics License Application ("BLA") supplement for toripalimab in combination with chemotherapy for the first-line treatment of advanced NSCLC. The BLA for toripalimab in combination with gemcitabine and cisplatin for the first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma ("NPC") and toripalimab monotherapy for the second-line or above treatment of recurrent or metastatic NPC after platinum-containing chemotherapy is currently under priority review by the FDA.

"The achievement of an overall survival benefit in non-small cell lung cancer patients by toripalimab is a watershed event in the strategic transformation of Coherus and validates the role of toripalimab as the foundation of our immuno-oncology pipeline," said Denny Lanfear, CEO of Coherus. "Toripalimab has once again delivered positive progression free survival and overall survival clinical data in a first-line setting. We will now work closely with our partners at Junshi Biosciences to engage the FDA on BLA supplement filing strategies for first-line treatment of non-small cell lung cancer. We also look forward to initiating future studies combining toripalimab with a series of complementary immuno-oncology agents to advance patient care and outcomes in oncology."

"The results of CHOICE-01, demonstrating improvements in overall survival, confirm that toripalimab can deliver significant benefits to patients receiving first-line treatment for non-small cell lung cancer," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "With a consistently strong record of positive efficacy and safety accumulating as data read out from studies across multiple tumor types, we are working to register toripalimab for a broad array of indications in China and the United States. In 2022, we look forward to clinical data from additional Phase 3 studies in NSCLC, small cell lung cancer, triple negative breast cancer, and hepatocellular cancer."

About CHOICE-01
A total of 465 treatment-naive advanced NSCLC patients (220 squamous and 245 non-squamous) were randomized (2:1): 309 patients to the toripalimab plus chemotherapy arm and 156 to the placebo plus chemotherapy arm. The primary endpoint was PFS assessed by the investigator. Secondary endpoints included PFS assessed by a blinded independent review committee (BIRC), overall survival (OS), objective response rate (ORR) and duration of response (DoR). Patients in the placebo plus chemotherapy arm were actively crossed-over to toripalimab treatment at disease progression. The addition of toripalimab to standard first-line chemotherapy in patients with advanced NSCLC showed a manageable safety profile with no new safety signals observed.

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®). Currently, there are 4 approved indications for toripalimab in China:

1. second-line treatment of unresectable or metastatic melanoma;
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 the first and second indications (melanoma and NPC).

In addition, two supplemental New Drug Applications (NDAs) for toripalimab were accepted by the National Medical Products Administration (NMPA) for review in China:

- first-line treatment of patients with advanced or metastatic esophageal squamous cell carcinoma (ESCC).

- in combination with chemotherapy as the first-line treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC) with no EGFR or ALK tumor aberrations.

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. Earlier, the FDA granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the first-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 the treatment of 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 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 over 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.

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 in the United States and Canada 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, statements regarding Coherus' ability to generate cash flow from its UDENYCA® business; Coherus' plans to invest the cash generated by its biosimilar commercial business to build an immuno-oncology franchise; Coherus' ability to establish a leading position in the immuno-oncology field in the future; Coherus' and Junshi Biosciences' ability to co-develop toripalimab for NSCLC or other indications, Coherus' ability to commercialize toripalimab, or any other drug candidates developed as part of its collaboration with Junshi Biosciences in the licensed territory; the benefits of checkpoint inhibitors; Coherus initiating future studies combining toripalimab with a series of complementary immuno-oncology agents; the results of those future studies; the potential for toripalimab to gain approval in the United States for nasopharyngeal carcinoma, lung cancer, or any indication; registering toripalimab for a broad array of indications in China and the United States; future clinical data from additional Phase 3 studies in NSCLC, small cell lung cancer, triple negative breast cancer, and liver cancer; and 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; risks regarding the current status of the COVID-19 outbreak and the effect it can have on delaying or interrupting key clinical trial activities; the risks and uncertainties of the regulatory approval process, including the timing of Coherus' regulatory filings; risks in obtaining sufficient financing for contemplated clinical trials; 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; risks related to Coherus' collaboration with Junshi Biosciences; risks of the drug development position of Coherus' competitors; 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 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 subsequent Quarterly Reports on Form 10-Q, including the sections therein captioned "Risk Factors," and in other documents we file with the Securities and Exchange Commission.

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