Coherus and Junshi Biosciences to Present Positive Progression Free Survival and Overall Survival Results from JUPITER-06, a Phase 3 Clinical Trial Evaluating Toripalimab in Combination with Chemotherapy as First-Line Treatment for Advanced Esophageal Squamous Cell Carcinoma

Sep 16, 2021

- Interim results to be presented September 17 at the European Society for Medical Oncology (ESMO) Congress 2021 -

- Data support the use of toripalimab with chemotherapy as first-line therapy for patients with ESCC –

- Coherus and Junshi Biosciences plan to submit a BLA supplement for 1L ESCC in 2022 –

SHANGHAI, China, and REDWOOD CITY, Calif., Sept. 16, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS) and Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", HKEX: 1877; SSE: 688180) today announced positive interim results from the pivotal study "JUPITER-06" (NCT03829969), a randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating toripalimab in combination with chemotherapy as a first-line therapy for patients with advanced or metastatic esophageal squamous cell carcinoma (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.

The results will be summarized by Dr. Feng Wang, Professor at Sun Yat-sen University Cancer Center (SYUCC), Guangzhou, in a mini-oral session during the ESMO Congress 2021 on Friday, September 17, 2021 at 12:05 pm Eastern Time. The abstract (#1373MO) is now available on the ESMO website.

"The findings of this interim analysis provide strong evidence that the addition of toripalimab to chemotherapy as a first-line treatment for advanced or metastatic ESCC patients has superior PFS and OS than chemotherapy alone," said Dr. Wang. "We look forward to updated analyses of overall survival of the JUPITER-06 study in the future and believe that these results will build a strong argument to support the use of toripalimab in combination with chemotherapy as a new standard first-line treatment in patients with advanced or metastatic ESCC."

"A strong and consistent efficacy and safety profile is emerging for toripalimab across multiple tumor types as data read out from pivotal clinical trials in melanoma, nasopharyngeal carcinoma, urothelial cancer, lung cancer and now also esophageal squamous cell carcinoma," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "We believe toripalimab could be a potential new treatment choice where patients truly need better options. We will collaborate with Coherus to advance a BLA supplement for ESCC to make toripalimab available as quickly as possible for these patients in the U.S."

"With JUPITER-06, toripalimab has once again exhibited compelling efficacy in a first-line setting," said Denny Lanfear, CEO of Coherus. "The significant PFS and similarly robust overall survival data demonstrate that toripalimab in combination with chemotherapy could provide significant clinical benefits to patients with advanced or metastatic esophageal squamous cell carcinoma. We plan to work closely with our partner, Junshi Biosciences, to pursue a BLA supplement for this new indication expeditiously."

About JUPITER-06
A total of 514 treatment-naive advanced or metastatic patients were randomized (1:1) to receive toripalimab or placebo in combination with paclitaxel plus cisplatin chemotherapy followed by toripalimab or placebo maintenance. The primary endpoints were PFS as assessed by a blinded independent central review (BICR) and overall survival (OS).

- At a prespecified interim analysis on March 22, 2021, with median follow-up of 7.4 and 7.3 months in the two arms, there was a significant improvement in OS for the toripalimab-chemotherapy arm compared to the placebo-chemotherapy arm (HR=0.58 [95% CI: 0.43-0.78], P=0.00037) with median OS of 17.0 vs. 11.0 months;
- One-year OS rates were 66.0% vs.43.7% for the toripalimab-chemotherapy arm compared to the placebo-chemotherapy arm, respectively;
- A significant improvement in PFS assessed by BICR was also detected for the toripalimab-chemotherapy arm compared to the placebo-chemotherapy arm (HR=0.58 [95% CI: 0.46-0.74], P<0.00001);
- The OS and PFS benefits were observed across key subgroups, including all PD-L1 expression subgroups;
- The incidence of Grade ≥3 adverse events (AEs) (73.2% vs 70.0%) and fatal AEs (8.2% vs 8.2%) were similar between the two arms. No new safety signals were observed.

Junshi Biosciences and Coherus are planning in 2022 to submit a biologics license application supplement to the United States Food and Drug Adminstration for toripalimab for first-line treatment, in combination with platinum-based chemotherapy, of advanced or metastatic ESCC. In China, the supplemental New Drug Application of this indication has been accepted by the National Medical Products Administration (NMPA) in July, 2021.

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 efficacy and

safety 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 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 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 designation for toripalimab in combination with chemotherapy for the 1st line treatment of recurrent or metastatic NPC and also for toripalimab monotherapy in second or third line 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 designations 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 Coherus and Junshi to file a BLA in the United States for toripalimab for ESCC in 2022; the potential for Coherus and Junshi to file additional BLAs in the United States for toripalimab over the next three years for multiple rare cancers and highly prevalent cancers; the potential for toripalimab to gain approval in the United States for nasopharyngeal carcinoma, lung cancer, esophageal squamous cell carcinoma, or any 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 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.