Coherus Announces Toripalimab Achieved Primary Endpoints of Progression Free Survival and Overall Survival in Interim Analysis of Phase 3 Clinical Trial in First-Line Esophageal Squamous Cell Carcinoma

REDWOOD CITY, Calif., April 23, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq: CHRS) has received notice from immuno-oncology partner Junshi Biosciences that the Independent Data Monitoring Committee of the JUPITER-06 clinical trial has determined that toripalimab, an anti-PD-1 monoclonal antibody, in combination with paclitaxel/cisplatin as first-line treatment for patients with advanced esophageal squamous cell carcinoma (ESCC), has achieved the pre-specified primary endpoints of progression free survival (PFS) and overall survival (OS) at the interim analysis. JUPITER-06 is a randomized, double-blind, placebo-controlled, multi-center, phase 3 clinical trial initiated in 2019 with 514 patients enrolled.

The interim analysis showed that toripalimab, in combination with paclitaxel/cisplatin, significantly prolonged the PFS and OS of patients with advanced ESCC, compared with paclitaxel/cisplatin chemotherapy alone. Data from the study are expected later this year.

Earlier in 2021, Coherus in-licensed rights to develop and commercialize toripalimab in the United States and Canada. More than 2,100 patients have received toripalimab treatment in clinical trials, and pivotal clinical trials are ongoing or completed evaluating toripalimab for a broad range of tumor types including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney and skin. In the U.S., 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. 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. 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 Esophageal Squamous Cell Carcinoma (ESCC)
Esophageal cancer is a primary malignant tumor of the esophageal mucosa epithelium. ESCC and adenocarcinoma are the two main histological subtypes of esophageal cancer. Approximately 6,000 patients in the United States are diagnosed annually with esophageal squamous cell carcinoma. The current standard first-line treatment is platinum-based chemotherapy. The prognosis of patients with advanced ESCC is poor with five-year survival rates of less than 20%.

About JUPITER-06 Study
JUPITER-06 is a randomized, double-blind, placebo-controlled, multicenter phase 3 clinical trial evaluating the efficacy and safety of toripalimab combined with paclitaxel/cisplatin versus placebo combined with paclitaxel/cisplatin as first-line treatments for advanced esophageal squamous cell carcinoma. The JUPITER-06 Clinicaltrials.gov identifier is NCT03829969. Professor Ruihua Xu from the Sun Yat-sen University Cancer Hospital is the principal investigator of the JUPITER-06 study. A total of 514 patients were enrolled in the study. The primary endpoints are PFS as assessed by the Blinded Independent Review Committee and OS. Secondary endpoints include the PFS assessed by investigator, objective response rate, disease control rate and duration of response.

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.

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' 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; 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 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.

Coherus BioSciences Contact Information:

IR Contact
McDavid Stilwell
Coherus BioSciences, Inc.
IR@coherus.com

Media Contact
Denise Powell
denise@redhousecomms.com

Source: Coherus BioSciences, Inc.