Coherus to Present Data from a Phase 1 Dose Expansion Study of CHS-114, a Cytolytic Antibody Targeting Chemokine Receptor 8 (CCR8), at the 2025 American Association for Cancer Research (AACR) Annual Meeting

REDWOOD CITY, Calif., March 25, 2025 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus,” NASDAQ: CHRS), a commercial-stage innovative oncology company, today announced that an abstract highlighting interim data from its ongoing Phase 1 clinical trial evaluating CHS-114, a selective, cytolytic anti-CCR8 antibody, as monotherapy and in combination with toripalimab in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC), has been selected for a poster presentation at the upcoming 2025 AACR Annual Meeting, being held April 25-30, 2025, at McCormick Place Convention Center in Chicago, Illinois.

AACR 2025 Presentation Details

Title: Phase 1 study of anti-CCR8 antibody CHS-114 with and without anti-PD-1 antibody toripalimab in patients with advanced solid tumors
Lead Author: Francis Worden, M.D., *University of Michigan*
Abstract #: CT038
Poster Session: Phase 0 and Phase 1 Clinical Trials
Poster Section 49: Poster board 17
Date and Time: Monday, April 28, 2025, 9:00 a.m. – 12:00 p.m. CDT

About the CHS-114 Phase 1 Study

The Phase 1 study (NCT05635643) is a dose escalation, dose optimization and expansion study evaluating CHS-114 as a monotherapy and in combination with toripalimab, a next generation PD-1 inhibitor. Cohort 1a enrolled 20 patients with advanced solid tumors including 2 patients with HNSCC and evaluated multiple dose levels (5-1200 mg) of CHS-114 monotherapy. Cohort 1b evaluated two pharmacologically active doses of CHS-114 monotherapy in 12 HNSCC patients with paired tumor biopsies. Cohort 2 evaluated two pharmacologically active doses of CHS-114 with toripalimab in 7 patients. Primary objectives are to optimize the CHS-114 dose(s) for expansion and evaluate the safety of CHS-114 with toripalimab. Secondary objectives were to evaluate the safety, PK and antitumor activity of CHS-114 with and without toripalimab and assess biomarkers including changes in regulatory T cells (Tregs) and CD8+ T cells in paired tumor biopsies and other immune biomarkers.

About CHS-114

CHS-114, an afucosylated, cytolytic CCR8 monoclonal antibody, is designed to selectively target human CCR8 and preferentially kill CCR8+ Tregs within the tumor microenvironment while preserving CD8+ effector T cells and Tregs in normal tissue. In preclinical studies, CHS-114 induced antibody-dependent cellular cytotoxicity (ADCC) and/or antibody-dependent cellular phagocytosis (ADCP) to deplete tumoral CCR8+ Tregs. In addition, treatment with CHS-114 alone reduced tumor growth in murine models, and enhanced antitumor activity was observed in combination with anti-PD-1 treatment. CHS-114 is currently being evaluated in two Phase 1 clinical trials as monotherapy with and without toripalimab in advanced solid tumors, including head and neck cancer (NCT05635643) and gastric cancer (NCT06657144).

About Coherus BioSciences

Coherus is a fully integrated commercial-stage innovative oncology company with an approved next-generation PD-1 inhibitor, LOQTORZI® (toripalimab-tpzi), with growing revenues and a promising pipeline that includes two mid-stage clinical candidates targeting liver, lung, head & neck, and other cancers. Our strategy is to grow sales of LOQTORZI in nasopharyngeal carcinoma and advance the development of new indications for toripalimab in combination with both our pipeline candidates as well as our partners’, driving multiple development and sales synergies from proprietary combinations.

Coherus’ immuno-oncology pipeline includes multiple antibody immunotherapy candidates focused on enhancing the innate and adaptive immune responses to enable a robust antitumor immunologic response and enhance outcomes for patients with cancer. Casdozokitug is a novel IL-27 antagonistic antibody currently being evaluated in three ongoing clinical studies: a Phase 1/2 study in advanced solid tumors including combination with toripalimab in NSCLC, a Phase 2 study in HCC, and randomized Phase 2 study in HCC evaluating casdozokitug in combination with toripalimab and bevacizumab. CHS-114 is a highly selective, competitively positioned, cytolytic anti-CCR8 antibody currently in a Phase 1 study in patients with advanced solid tumors, including HNSCC and gastric cancer.

Coherus markets LOQTORZI, a novel next-generation PD-1 inhibitor, and UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta. In December 2024, Coherus announced the planned divestiture of its UDENYCA franchise. The transaction is expected to close late in the first quarter or early in the second quarter of 2025.

Neulasta® is a registered trademark of Amgen, 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’ expectations about identifying synergies between its I-O pipeline and its commercial operations; Coherus’ projections that its I-O pipeline will be able to enhance outcomes for cancer patients; and Coherus’ statements about its expectations about consummating the proposed transaction for the divestiture of the UDENYCA franchise at all or in the estimated time frame.

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 related to Coherus’ existing and potential collaboration partners; risks of Coherus’ reliance on third-parties; the risks and uncertainties related to manufacturing and supply of Coherus’ products, the risks and uncertainties of the regulatory approval process, including the speed of regulatory review and the timing of Coherus’

regulatory filings; uncertainties as to the timing for completion of the proposed transaction; uncertainties as to the Company's ability to satisfy all conditions required to consummate the proposed transaction for the divestiture of UDENYCA; the possibility that competing offers will be made by third parties; the occurrence of any event, change or other circumstance that may give rise to a right of one or both parties to terminate the agreement to divest UDENYCA; the possibility that the proposed transaction for the divestiture of UDENYCA may not be completed in the time frame expected by the Company or at all. All forward-looking statements contained in this press release speak only as of the date of this press release. Unless required by law, the Company is not under any duty and undertakes no obligation to publicly update or revise any forward-looking statement to reflect changes in underlying assumptions or factors, of new information, data or methods, future events or other changes. For a further description of the significant 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' Quarterly Report on Form 10-Q for the fiscal year ended December 31, 2024 filed with the Securities and Exchange Commission (SEC) on March 17, 2025, including the section therein captioned "Risk Factors" and in other documents Coherus files with the SEC including the proxy statement of the Company relating to the proposed transaction for the divestiture of UDENYCA filed with the SEC on January 28, 2025.

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