Coherus Presents Promising Early Clinical Data from Phase 1 Dose Expansion Study of CHS-114 in Patients with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma at AACR 2025

– CHS-114 demonstrates clinical efficacy and proof of mechanism in HNSCC in combination with toripalimab –

– Confirmed partial response in heavily pretreated PD-1 refractory patient supports expansion in HNSCC and gastric cancer in combination with toripalimab –

– A second-line Phase 1 dose optimization study in HNSCC and gastric cancer is ongoing; results expected in the first half of 2026–

– Coherus to host investor and analyst call with study investigator, Dr. Douglas Adkins, Washington University, today at 4:30 p.m. Eastern Time–

REDWOOD CITY, Calif., April 28, 2025 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus,” NASDAQ: CHRS), today announced 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) evaluating two pharmacologically active doses of CHS-114 for dose optimization. These data are being presented at the 2025 American Association for Cancer Research (AACR) Annual Meeting, taking place April 25-30, 2025, in Chicago, Illinois.

The data showed a confirmed partial response in a heavily pretreated PD-1 refractory patient, a > 50% depletion in CCR8+ Treg, and an increase in CD8+ T cells, consistent with anti-tumor activity and demonstrating proof of mechanism. Importantly, the safety profile was consistent with advanced disease and the known safety profile of toripalimab. These data support continued evaluation of CHS-114 in combination with other therapies, including toripalimab. Results support advancement and ongoing enrolment in Part 3 of the study evaluating CHS-114 with toripalimab in HNSCC (n = 40).

CHS-114 is an afucosylated CCR8 monoclonal antibody and is the only known selective molecule designed to exclusively target human CCR8 with no off-target binding and preferentially kills CCR8+ Tregs within the tumor microenvironment while preserving CD8+ effector T cells and Tregs in normal tissue.

“The data to date demonstrate a robust depletion of Treg cells in tumors, with a manageable safety profile, and a patient with a meaningful clinical response, which is highly encouraging,” said Rosh Dias, M.D., Coherus’ Chief Medical Officer. “Furthermore, the profound increase in CD8+ T cells, making these tumors immunologically hot, is exciting as it supports CHS-114 being combined with several treatment modalities including T Cell Engagers. Head and neck cancer is an important strategic focus for Coherus, but CHS-114 has the potential, based on its mechanism of action, to treat many solid tumors, including non-small cell lung cancer and other large, underserved immuno-oncology indications, like colorectal cancer. We look forward to sharing further head and neck and gastric cancer data in the first half of next year.”

“One of the biggest challenges in oncology has been finding a treatment that depletes Treg cells and relieves immune suppression in the tumor without causing collateral autoimmune disease or affecting antitumor T cells,” said Douglas Adkins, M.D., Professor of Medicine, Director, Section of Head and Neck and Thyroid Medical Oncology, Division of Medical Oncology, Washington University School of Medicine. “These early clinical results are exactly what we’ve been hoping for and demonstrate CHS-114’s ability to remodel the tumor microenvironment in favor of anti-tumor activity. I am looking forward to exploring this treatment combination for solid tumor patients, even beyond head and neck.”

Results from Phase 1b dose expansion trial evaluating CHS-114 monotherapy and with toripalimab in HNSCC

This open-label Phase 1b clinical trial evaluated CHS-114 as a single-agent and in combination with toripalimab in 21 patients with advanced solid tumors including HNSCC. Patients received either CHS-114 alone or in combination with toripalimab (240 mg) q3w. The primary endpoint of the study was to determine dose limiting toxicities (DLTs) and treatment emergent adverse events (TEAEs), with the goal of identifying two recommended doses for expansion. Key secondary endpoints included objective response rate (ORR) based on investigator review per RECIST v1.1 as well as pharmacokinetics and pharmacodynamics (PK/PD).

As of the data cutoff date of January 24, 2025:

- CHS-114 monotherapy demonstrated Treg cell depletion (range of decrease: 52-97%), and significant increase in CD8+ T cells in the tumor, establishing proof of mechanism and confirming the doses are pharmacologically active.
  - CHS-114 with toripalimab had promising antitumor activity in HNSCC that warrants continued exploration.
  - CHS-114 administration leads to a substantial increase in CD8+ T cells in the tumor microenvironment, providing a strong rationale for combining with toripalimab and other drugs such as T cell engagers and bispecifics.
- A confirmed partial response was achieved in the high dose cohort of CHS-114 in combination with toripalimab in a heavily pre-treated PD-1 refractory patient (PD-L1 low), demonstrating CHS-114 in combination with toripalimab can potentially overcome PD-1 resistance.
- CHS-114 with and without toripalimab had a manageable safety profile in HNSCC patients, with TEAEs consistent with advanced disease and the known safety profile of toripalimab.
- Two CHS-114 doses were selected for dose optimization based on safety, peripheral CCR8+ Treg depletion, PK and biomarker data.

These results support continued evaluation of CHS-114 in combination with other drugs including toripalimab, with broad potential applications in many solid tumors with a high density of CCR8+ Treg cells. A second-line HNSCC dose optimization study of CHS-114 in combination with toripalimab in HNSCC and gastric cancer patients is ongoing, with anticipated results in the first half of 2026 The current study design is expected to address the regulatory requirements under Project Optimus[1] and support the recommendation of a phase 2 dose by early 2026.

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

Conference Call Information for Investors and Analysts

Coherus Chief Development Officer, Dr. Theresa LaVallee, and Chief Medical Officer, Dr. Rosh Dias, will host a presentation and discussion of new clinical data from the Phase 1 study with CHS-114 with and without anti-PD-1 antibody toripalimab with study investigator, Dr. Douglas Adkins of Washington University.

When: Monday, April 28, 2025, starting at 4:30 p.m. Eastern Time

Investors and analysts are invited to listen into a live audio webcast of the presentation. To access the conference call, please pre-register through the following link to receive dial-in information and a personal PIN to access the live call: https://register-conf.media-server.com/register/BI5eb6be782f004f9bb4e652903aabafe4

Please dial in 15 minutes early to ensure a timely connection to the call.

Webcast: https://edge.media-server.com/mmc/p/yawixgnq

An archived webcast will be available on the "Investors" section of the Coherus website at https://investors.coherus.com/events-presentations.

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. Arm 1a (first-in-human dose escalation) enrolled 20 patients with advanced solid tumors including 2 patients with HNSCC and evaluated multiple dose levels (5-1200 mg) of CHS-114 monotherapy. Arm 1b evaluated two pharmacologically active doses of CHS-114 monotherapy in 12 HNSCC patients with paired tumor biopsies. Arm 2 evaluated two pharmacologically active doses of CHS-114 with toripalimab in 7 patients. Arm 3 is evaluating two pharmacologically active doses of CHS-114 with toripalimab in 40 patients with second-line HNSCC. 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 combination with toripalimab in two Phase 1b clinical trials in patients with 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), 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 LOQTORZI in combination with both our pipeline candidates as well as our partners', driving sales multiples and 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 response and enhance outcomes for patients with cancer. Casdozokitug is a novel IL-27 antagonistic antibody currently being evaluated in multiple Phase 1/2 and Phase 2 studies in patients with advanced solid tumors including in non-small cell lung cancer and in hepatocellular carcinoma. CHS-114 is a highly selective cytolytic anti-CCR8 antibody currently in Phase 1 studies in patients with advanced solid tumors, including head and neck squamous cell carcinoma and gastric cancer.

For more information about LOQTORZI, including the U.S. Prescribing Information and important safety information, please visit www.loqtorzi.com.

Forward-Looking Statements

The statements in this press release include express or implied forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act about Coherus that involve risks and uncertainties relating to future events and the future performance of Coherus. Forward-looking statements relate to expectations, beliefs, projections, future plans and strategies, anticipated events or trends and similar expressions concerning matters that are not historical facts. Words such as "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "future," "opportunity," "likely," "target," variations of such words, and similar expressions or negatives of these words are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. You can also identify forward-looking statements by discussions of strategy, plans or intentions.

Examples of such forward-looking statements include, but are not limited to, express or implied statements regarding: the ability of Coherus' pipeline to enhance outcomes for cancer patients; expectations about future synergies; projections about growth in sales; expectations for announcements about data or progress based on Coherus' clinical trials in the future; and the assumptions underlying or relating to such statements.

These forward-looking statements are based on Coherus' current plans, estimates and projections. By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific, assumptions and changes in circumstances, many of which are beyond the control of Coherus. A number of important factors, including those described in this press release, could cause actual results to differ materially from those contemplated in any forward-looking statements. Factors that may affect future results and may cause these forward-looking statements to be inaccurate include, without limitation: uncertainties about the potential impact of unforeseen liabilities, future capital expenditures, revenues, costs,

expenses, earnings, economic performance, indebtedness, financial condition and losses on Coherus' future prospects, business and operations in the future; risks and uncertainties of conducting clinical trials; and risks and uncertainties of any litigation, regulatory actions and other legal proceedings.

While the foregoing list of factors presented here is considered representative, no list should be considered to be a complete statement of all potential risks and uncertainties. There can be no assurance that the transaction described above will in fact be consummated in the manner described or at all. For a further discussion of these and other factors that could cause Coherus' future results to differ materially from any forward-looking statements see the section entitled "Risk Factors" in Coherus' Annual Report on Form 10-K for the period ended December 31, 2024, filed with the Securities and Exchange Commission (SEC) on March 17, 2025, as updated by Coherus' subsequent reports filed with the SEC. Any forward-looking statements speak only as of the date of this press release and are made based on the current good faith beliefs and judgments of Coherus' management, and the reader is cautioned not to rely on any forward-looking statements made by Coherus. Unless required by law, Coherus 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.

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References

[1]Project Optimus: Reforming the dose optimization and dose selection paradigm in oncology

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