



Coherus Oncology Presents at SITC Clinical Multiomic Biomarker Data for CHS-114, a Highly Selective anti-CCR8 Cytolytic Antibody

– CHS-114 demonstrated robust and selective depletion of CCR8+ Tregs as well as favorable immune remodeling in tumor tissue from head and neck squamous cell carcinoma (HNSCC) patients –

– CHS-114 administration resulted in selective depletion of CCR8+ Tregs and a >50% increase in intratumoral CD8 T cells – turning tumors “hot”

REDWOOD CITY, Calif., Nov. 07, 2025 (GLOBE NEWSWIRE) -- Coherus Oncology, Inc. (NASDAQ: CHRS), today announced new multiomic tumor and blood-based biomarker data from the dose expansion arm of its ongoing Phase 1b clinical trial evaluating CHS-114, a selective, cytolytic anti-CCR8 antibody, as monotherapy and in combination with toripalimab in patients with recurrent/metastatic HNSCC. These data are being presented at the 40th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) being held November 5-9, 2025, in National Harbor, Maryland.

This interim analysis from the dose expansion phase demonstrates that CHS-114-mediated immune activation is significantly enhanced and sustained with toripalimab in HNSCC study participants. In on-treatment tumor biopsies, CHS-114 depleted CCR8+ Tregs, but not CCR8- Tregs, and increased CD8+ T cells in the tumor microenvironment (TME), indicating TME remodeling for antitumor immune activation and establishing proof of mechanism. To date, CHS-114, as monotherapy or in combination with toripalimab has a manageable safety profile, with promising early antitumor activity in HNSCC.

“These data extend the data we presented at AACR and are important for 3 key development aims. Firstly, showing selective depletion of CCR8+ Tregs and not CCR8- Tregs or CD8 and CD4 T cells, shows the drug does what it was intended to do. This coupled with the acceptable safety profile further supports that CCR8 is proving to be a tumor selective target that now allows the field to remove Tregs in cancer. Secondly, showing statistically significant increase in immune activation using multiple biomarker assays further supports the development plan to advance CHS-114 in combination with toripalimab or with other immune activators. Importantly, we have seen a partial response in a refractory head and neck cancer patient in the initial testing of the safety of this combination,” said Theresa LaVallee, Ph.D., Coherus Oncology’s Chief Scientific and Development Officer. “And third, the data support the 2 doses of CHS-114 are pharmacologically active leading to substantial Treg depletion in tumors and immune activation. The ongoing enrollment in the dose optimization arm of the study, evaluating CHS-114 and toripalimab, sets us up to address the FDA’s Project Optimus and define a phase 2 dose.”

Multiomic Clinical Biomarker Data from CHS-114 Phase 1 Dose Expansion and Safety Arms in HNSCC Participants

Immune profiling of blood from HNSCC participants from 2 pharmacologically active doses of CHS-114 monotherapy expansion arm (n=10) and in combination with toripalimab safety arm (n=6) showed:

- CHS-114 demonstrated robust depletion of target CCR8+ Tregs and spared non-CCR8+ Tregs, CD4+ T cells and CD8+ T cells in PBMCs from HNSCC participants throughout the treatment cycle.
- CHS-114 demonstrated significant increases in peripheral immune activation of CD8+ T cell cytotoxicity, activation and proliferation and inflammatory cytokine levels compared with pretreatment levels.
- CHS-114 with toripalimab mediated a robust and significant increase in CD8+ T cell proliferation (Ki67) and Th1 inflammatory cytokines that was sustained through the dosing cycle.

Immune profiling of pretreatment and on-treatment tumor tissue tumor tissue samples from HNSCC participants from monotherapy expansion (n=10) and combination with toripalimab (n=2) cohorts showed:

- CHS-114 treatment decreased CCR8+ Treg density by 74% and total FOXP3+ Treg density by 43%, while sparing CCR8- Tregs demonstrating selective and robust depletion of target Tregs.
- Furthermore, CHS-114 treatment increased CD8+ T cell density by 73% and CD8+ T cell /CCR8+ Treg ratio by 12-fold, demonstrating a remodeling of the TME.
- Data confirm CHS-114 selectivity, the 2 doses evaluated are pharmacologically active and establish proof of mechanism in tumor tissue.

SITC 2025 Presentation Details

Abstract # 640: [CHS-114, an anti-CCR8 cytolytic monoclonal antibody demonstrates selective intratumoral Treg depletion and favorable immune remodeling in participants with advanced solid tumors.](#)

- Date: Saturday, November 8, 2025, 10 a.m. – 6:35 p.m. ET
- Location: Prince George ABC Exhibit Halls, Gaylord National Resort and Convention Center

About the CHS-114 Phase 1/1b 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 13 HNSCC patients with required paired tumor biopsies. Arm 2 evaluated the safety of 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 of the Phase 1 study are to optimize the CHS-114 dose(s) for expansion and

evaluate the safety of CHS-114 with and without toripalimab. Secondary objectives are to evaluate the preliminary antitumor activity and the PK 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), colorectal cancer, gastric cancer, and esophageal cancer (NCT06657144).

About Coherus Oncology

Coherus Oncology 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 proprietary pipeline that includes two mid-stage clinical candidates targeting liver, lung, head & neck, colorectal and other cancers. The Company's strategy is to grow sales of LOQTORZI in nasopharyngeal carcinoma and advance the development of new indications for LOQTORZI in combination with both its pipeline candidates as well as its 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 non-small cell lung cancer and HCC. CHS-114 is a highly selective cytolytic anti-CCR8 antibody currently in Phase 1b/2a studies in patients with advanced solid tumors, including head and neck cancer, colorectal cancer, gastric cancer, and esophageal 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 the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934 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 future enrollment in clinical trials; projections about the expansion of indications for LOQTORZI; and the assumptions underlying or relating to such statements.

These forward-looking statements are based on Coherus' current plans, beliefs, 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' prospects, business and operations in the future; risks and uncertainties in executing collaboration agreements and other joint ventures; risks and uncertainties of conducting clinical trials; the risks of Coherus' dependence on an ability to raise funds, which may not be available on acceptable terms or at all; 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. 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' Quarterly Report on Form 10-Q for the period ended September 30, 2025, filed with the Securities and Exchange Commission (SEC) on November 6, 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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