Coherus Presents Data from Next-generation Immuno-oncology Programs at 38th Annual Meeting of Society for Immunotherapy of Cancer (SITC)

– Data demonstrate distinct IL-27-mediated expression of genes associated with immune suppression in vitro, supporting ongoing clinical development of first-in-class anti-IL-27 antibody casdozokitug –

– Anti-CCR8 antibody, CHS-114, depletes tumor-infiltrating Treg cells and activates NK cells in dissociated head and neck squamous cell carcinoma (HNSCC) tumors –

– Anti-PD-1 antibody, LOQTORZI™ (toripalimab-tpzi), exhibits potent T cell activation; in combination with chemotherapy shows enhanced clinical efficacy irrespective of PD-L1 status across multiple tumor types –

REDWOOD CITY, Calif., Nov. 03, 2023 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Coherus, Nasdaq: CHRS), today announced data from three immuno-oncology pipeline programs at the 38th Annual Meeting of SITC taking place November 1 - 5, 2023 at the San Diego Convention Center in San Diego, CA. Preclinical data presented support differentiated mechanisms of its next-generation immunotherapies potentially enabling the antitumor immune activation in more cancer patients and enhanced treatment outcomes.

"These data presented at SITC highlight the complementary mechanisms that we have in our innovative immunotherapy portfolio, including anti-PD-1, anti-IL27 and anti-CCR8, and the promise of novel immuno-oncology treatment combinations that may overcome the challenging tumor microenvironment," said Theresa LaVallee, Ph.D., Coherus' chief development officer. "LOQTORZI ™ is the first approved treatment option for patients with nasopharyngeal carcinoma (NPC), and we will continue to generate and use data to optimize our clinical development plans through the selection of additional tumor types and immuno-oncology combinations that can have the greatest impact on extending survival for cancer patients."

Casdozokitug (CHS-388, formerly SRF388), a first-in-class anti-IL-27 antibody
Interleukin (IL)-27 is an immunoregulatory cytokine involved in resolving inflammation and inhibiting anti-tumor immune responses. Blocking IL-27 with casdozokitug in clinical trials has led to monotherapy tumor growth inhibition and partial responses in patients with non-small cell lung cancer (NSCLC) and renal cell carcinoma (RCC) (NCT04374877) and ongoing trials are studying combinations with PD-1/PD-L1 pathway blockade in NSCLC and hepatocellular carcinoma (HCC). Data presented at SITC 2023 demonstrate IL-27-mediated gene expression, highlighting its critical role in immune suppressive mechanisms in the tumor microenvironment and importance as a new target for cancer treatment, as well as an opportunity to identify biomarkers that could determine patients most likely to respond to anti-IL-27 treatment.

Abstract #1351: *Identifying IL-27 dependent biomarkers in lymphocytes, NK cells, and myeloid cells in peripheral blood and the tumor microenvironment*
Date and Time: Friday, November 3, 9 a.m.–7 p.m. Pacific Daylight Time (PDT)
Location: Exhibit Halls A and B1 – San Diego Convention Center

Poster presentation data are summarized as follows:

- In human immune cells from peripheral blood, IL-27 induces the expression of interferon (IFN)-stimulated genes, which are associated with drug resistance in cancer
- Although many known IFN-responsive genes were induced by both IFNs and IL-27 treatment, distinct gene expression was observed in different immune cell types
- IL-27 and IFNs induce unique gene expression in different cell types, for example, GBP5 (guanylate-binding protein 5) and IRF1 (interferon regulatory factor 1), two interferon stimulated genes, are preferentially elevated by IL-27 in NK cells and CD8+ T cells
- Immunohistochemistry (IHC) analysis of treatment-naïve NSCLC tumor samples showed that IL-27+ macrophages are co-localized with GBP5+ T-cell-rich areas in the TME
- These studies lend insights into the immune interplay between IFNs and IL-27 signaling across different immune cells and within the TME and ascertain the immunosuppressive role of IL-27 and may inform casdozo clinical development.

CHS-114 (formerly SRF114), an anti-CCR8 antibody
CCR8 is a chemokine receptor predominantly expressed by tumor infiltrating Tregs that suppress the body's natural anti-cancer immune response. Targeting CCR8 is a promising potential therapeutic strategy designed to deplete Tregs, reshape the tumor microenvironment and enhance anti-tumor immune response. CHS-114 is designed to selectively target human CCR8 and preferentially depletes $CCR8^+$ Treg cells and not T effector (Teff) cells in tumors or normal tissue. Data presented demonstrate the role of $CCR8^+$ Tregs as dominant immunosuppressive cells in the TME and highlight head and neck squamous cell carcinoma (HNSCC) as a promising tumor type in which CHS-114 could have anti-tumor activity as monotherapy or in combination with an anti-PD1 antibody. CHS-114 is currently being evaluated in a Phase 1 clinical trial (NCT05635643).

Abstract #1354: *Anti-CCR8 antibody SRF114 depletes tumor-infiltrating regulatory T cells in dissociated tumors from patients with head and neck squamous cell carcinoma*
Date and Time: Saturday, November 4, 9 a.m.–8:30 p.m. PDT
Location: Exhibit Halls A and B1 – San Diego Convention Center

Poster presentation data are summarized as follows:

- Chemokine receptor 8 (CCR8) expression is highly enriched on intratumoral Tregs within the TME cells, particularly in HNSCC
- In multiple model systems, CHS-114, a cytolytic antibody selective for CCR8, activates natural killer (NK) cells and specifically induces NK-mediated cytotoxicity against tumor-infiltrating CCR8+ Tregs and results in the expansion of

effector CD8 T cells
- Enhanced antitumor immunity is observed with combination of Anti-CCR8 and anti-PD-1 combination treatment
- CHS-114, a CCR8-specific cytotoxicity-inducing antibody that preferentially depletes CCR8+ Treg cells and not T effector (Teff) cells, is currently being evaluated in a Phase 1 clinical trial (NCT05635643).

LOQTORZI™ (toripalimab-tpzi), a next generation anti-PD-1 antibody
PD-L1 is a protein found on the surface of some cancer cells that can help evade the body's immune system by suppressing T cell activation and inhibiting the T cell's ability to kill cancer cells. LOQTORZI™ is an anti-PD-1 monoclonal antibody that blocks PD-L1 binding to the PD-1 receptor at a unique site with high affinity to activate antitumor immunity. Data presented compare mechanistic data for LOQTORZI™ to commercially available anti-PD-1 monoclonal antibodies and demonstrate higher expression of key immune system biomarkers with LOQTORZI™. Additionally, LOQTORZI™ in combination with chemotherapy shows enhanced clinical efficacy irrespective of PD-L1 status across multiple tumor types in post hoc analyses of 3 randomized controlled clinical trials in NPC, NSCLC and esophageal squamous-cell carcinoma (ESCC). LOQTORZI™ (toripalimab-tpzi) was recently approved by the U.S. Food and Drug Administration (FDA) for metastatic or recurrent NPC as first-line treatment in combination with chemotherapy or as second- or greater-line monotherapy treatment.

Abstract #468: Characteristics of toripalimab: a next generation anti-PD-1 antibody with potent T cell activation and enhanced clinical efficacy irrespective of PD-L-1 status
Date and Time: Saturday, November 4, 9 a.m.–8:30 p.m. PDT
Location: Exhibit Halls A and B1 – San Diego Convention Center

Poster presentation data are summarized as follows:

- Toripalimab in combination with chemotherapy demonstrates clinical efficacy irrespective of PD-L1 status
- Toripalimab exhibits a 12-fold higher binding affinity to PD-1 compared to pembrolizumab
- Toripalimab promotes a stronger Th1-mediated response than pembrolizumab *in vitro* in human peripheral blood mononuclear cells (PBMCs)
- Toripalimab induced an elevated IFN- gene signature in NSCLC dissociated tumor cells with different kinetics and higher intensity compared to pembrolizumab
- In comparison to other commercially available anti-PD-1 antibodies, toripalimab exhibits the lowest potential for partial agonism by recruiting low levels of SHP1 and SHP2, negative regulators of T cell activation

About LOQTORZI™ (toripalimab-tpzi)
LOQTORZI™ is a next generation anti-PD-1 monoclonal antibody that blocks PD-L1 binding to the PD-1 receptor at a unique site with high affinity and activates antitumor immunity demonstrating improvement in the overall survival of cancer patients in several tumor types.
For more information, please see LOQTORZI.com for FDA-approved indications and full prescribing information.

About Casdozokitug
Casdozokitug (formerly SRF388) is a first-in-class human anti-IL-27 antibody designed to inhibit the activity of this immunosuppressive cytokine. Particular tumor types have been identified where IL-27 appears to play an important role in the immunosuppressive tumor microenvironment and may contribute to resistance to treatment with checkpoint inhibitors. Furthermore, a potential biomarker associated with IL-27 has been identified that may be useful in helping identify patients most likely to respond to casdozokitug. It is the first IL-27 antibody to enter the clinic.

About CHS-114
CHS-114 (formerly SRF114) is a human, cytolytic anti-CCR8 antibody designed to preferentially deplete CCR8+ Treg cells within the tumor microenvironment and not T effector (Teff) calls in normal tissue. In preclinical studies, CHS-114 induced antibody-dependent cellular cytotoxicity (ADCC) and/or antibody-dependent cellular phagocytosis (ADCP) pathways to deplete intertumoral Treg cells. In addition, CHS-114 reduced tumor growth in murine models. CHS-114 is currently being evaluated in a Phase 1 clinical trial (NCT05635643) as a therapeutic candidate that holds the potential to drive anti-tumor immunity in patients.

About Coherus' Immuno-oncology Pipeline
Coherus is developing an innovative immuno-oncology pipeline that will be synergistic with its proven commercial capabilities in oncology. The foundational therapy in our immuno-oncology pipeline is LOQTORZI™ (toripalimab-tpzi), a next-generation, FDA-approved PD-1 inhibitor.

Through its acquisition of Surface Oncology, Coherus' immuno-oncology pipeline now includes multiple antibody immunotherapy candidates focused on enhancing the innate and adaptive immune responses to enable a robust immunologic response and enhance outcomes for patients with cancer. Casdozokitug (formerly SRF388) is a novel anti-IL-27 antibody currently being evaluated in Phase 1/2 clinical trials in lung and liver cancer. CHS-114 (formerly SRF114) is a highly selective, competitively positioned ADCC-enhanced anti-CCR8 antibody currently in a Phase 1/2 study as a monotherapy in patients with advanced solid tumors.

Coherus' earlier-stage immuno-oncology pipeline targets immune-suppressive mechanisms in the tumor microenvironment, including CHS-006, a TIGIT-targeted antibody, being evaluated in a Phase 1/2 clinical trial in combination with toripalimab in patients with advanced solid tumors, and CHS-1000, a preclinical program targeting the novel pathway ILT4.

About Coherus BioSciences
Coherus is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Coherus is developing an innovative immuno-oncology pipeline that will be synergistic with its proven commercial capabilities in oncology.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®, YUSIMRY™ (adalimumab-aqvh), a biosimilar of Humira® and expects to launch LOQTORZI™ (toripalimab-tpzi), a novel next generation PD-1 inhibitor, in the U.S. in Q1 2024.

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' ability to realize synergies between its commercial capabilities in oncology and its immuno-oncology pipeline; Coherus' expectations of the launch timing for LOQTORZI™; expectations about the timing and ability of Coherus to advance the development of its product candidates; and Coherus' expectation that its product candidates may advance treatment outcomes for patients.

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 integration of Surface's programs and operations; risks related to realizing the anticipated benefits of the acquisition of Surface; risks related to Coherus' existing and potential collaboration partners; risks of Coherus' competitive position; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review, international aspects of Coherus' business and the timing of Coherus' regulatory filings; the risk of FDA review issues; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' products and product candidates; and the risks and uncertainties of possible litigation. All forward-looking statements contained in this press release speak only as of the date of this press release. Coherus undertakes no obligation to update or revise any forward-looking statements. 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 quarter ended June 30, 2023 filed with the Securities and Exchange Commission on August 2, 2023, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission.

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