Coherus Announces Toripalimab Data at 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics

— Data demonstrate preclinical potent T cell activation and differentiated mechanism of action and enhanced clinical efficacy irrespective of PD-L1 status when administered in combination with chemotherapy —

— Toripalimab demonstrated twelve-fold higher binding affinity to PD-1 compared to pembrolizumab —

— In vitro studies show significantly higher activation of T cells compared to pembrolizumab in multiple assay systems —

REDWOOD CITY, Calif., Oct. 14, 2023 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS), today announced a presentation of toripalimab data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics being held October 11-15, 2023 at the Hynes Convention Center in Boston.

PD-L1, a protein found on the surface of some cancer cells, suppresses T cell activation and inhibits the ability of the body's immune system to kill cancer cells. Toripalimab is an anti-PD-1 monoclonal antibody that binds with high affinity to a unique site on PD-1, thereby blocking the interaction of PD-1 and PD-L1. Preclinical mechanistic data demonstrate statistically significantly higher activation of T cells and higher expression of key immune system activators with toripalimab compared to pembrolizumab, clinically a widely used anti-PD-1 monoclonal antibody for the treatment of cancer patients. These data may provide a mechanistic explanation for the improvements in overall survival irrespective of PD-L1 expression levels observed in clinical trials in multiple tumor types evaluating toripalimab in combination with chemotherapy. A biologics license application (BLA) for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma (NPC) is currently under review by the U.S. Food and Drug Administration (FDA).

"PD-1 inhibition has been a significant advancement in cancer treatment across tumor types but better treatments are needed to increase response rates and drive improved outcomes for patients. These data support toripalimab as a next-generation PD-1 inhibitor that, in combination with chemotherapy, may have greater antitumor activity in less inflamed tumors than more commonly used PD-1 inhibitors in certain cancers due to its unique binding properties," said Theresa LaVallee, Ph.D., Coherus' chief development officer. "We look forward to delivering this important new treatment option to patients, first in NPC, if approved, and continuing to evaluate its efficacy in combination with chemotherapy in multiple cancer types and in combination with novel I-O agents."

Poster presentation data are summarized as follows:

- Toripalimab in combination with chemotherapy significantly improved overall survival irrespective of PD-L1 status in post hoc analyses of 3 randomized controlled clinical trials, including in NPC, non-small cell lung cancer (NSCLC) and esophageal squamous-cell carcinoma (ESCC)
- Toripalimab exhibits a 12-fold higher binding affinity for PD-1 compared to pembrolizumab that is driven by a slow-off rate
- Toripalimab is more potent than pembrolizumab in enhancing levels of Th1 cytokines and cytotoxicity in human peripheral blood mononuclear cells (PBMCs)
- In comparison to pembrolizumab, binding of toripalimab to PD-1 induced low levels of SHP1 and SHP2 recruitment, thereby minimizing a key process of T cell suppression
- Toripalimab induced and elevated IFN-γ gene signature in NSCLC dissociated tumor cells with different kinetics and intensity compared to pembrolizumab

Poster presentation details:

- Poster Number C069: *Toripalimab, an anti-PD-1 antibody that demonstrates potent T cell activation and enhanced clinical efficacy irrespective of PD-L1 status*
  Session: Poster Session C
  Date and time: Saturday, October 14, 12:30 pm-4:00 pm EDT
  Location: Level 2, Exhibit Hall D

About toripalimab
Toripalimab 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. The BLA for toripalimab in combination with chemotherapy as the first-line treatment for recurrent or metastatic NPC and toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy is under review by the FDA. In Europe, the marketing authorization applications (MAA) for toripalimab for the first-line treatment of NPC and esophageal squamous cell carcinoma (ESCC) are under review by the European Medicines Agency (EMA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA).

The FDA granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC in 2021 as well as for toripalimab monotherapy in the second or third-line treatment of recurrent or metastatic NPC in 2020. Additionally, the FDA has granted Fast Track designation for toripalimab for the treatment of mucosal melanoma and Orphan Drug designations for the treatment of ESCC, NPC, mucosal melanoma, soft tissue sarcoma, and small-cell lung cancer (SCLC).

More than 40 company-sponsored toripalimab clinical studies covering over fifteen indications have been conducted globally by Shanghai Junshi Biosciences Co., Ltd (Junshi Biosciences), including in China, the United States, Southeast Asia, and European countries. Ongoing or completed pivotal clinical trials evaluating the safety and efficacy of toripalimab cover a broad range of tumor types including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney, and skin.

About Coherus' Immuno-oncology Pipeline

Coherus is developing an innovative immuno-oncology pipeline that will be synergistic with its proven commercial capabilities in oncology. Through an in-licensing agreement with Junshi Biosciences, Coherus is developing toripalimab, an anti-PD-1 antibody, in the United States and Canada. A biologics license application for toripalimab for the treatment of NPC is under review by the FDA. Toripalimab is approved in China for the treatment of melanoma, urothelial cancer, esophageal squamous cell carcinoma, nasopharyngeal carcinoma and non-small cell lung cancer.

Through its recent 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 anti-CCR8 antibody currently in a Phase 1/2 study as a monotherapy in patients with advanced solid tumors. There are also two out-licensed partnership programs to advance its next-generation cancer therapies.

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' strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics.

In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. The Biologics License Application for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma is currently under review by the FDA.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®, and YUSIMRY™ (adalimumab-aqvh), a biosimilar of Humira®.

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 build its immuno-oncology franchise to achieve a leading market position; Coherus' ability to generate cash and net sales; Coherus' investment plans; Coherus' ability to find synergies between its I-O pipeline and its commercial operations; expectations about the efficacy and safety profile of any product candidate; and Coherus' ability to launch or achieve FDA approvals for any product candidate in the future.

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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Source: Coherus BioSciences, Inc.