Coherus Presents Phase 1/2 Clinical Data on Casdozokitug, a First-in-Class IL-27-Targeted Antibody, at the 2023 ESMO Immuno-Oncology Congress

Dec 6, 2023

– Casdozokitug has demonstrated anti-tumor activity alone and in combination with an anti-PD-1 antibody; two of nine squamous NSCLC patients had confirmed partial responses –

– Data support continued evaluation of casdozokitug in combination with anti-PD-1 antibody treatments including ongoing Phase 2 cohort of casdozokitug with toripalimab in treatment refractory NSCLC –

REDWOOD CITY, Calif., Dec. 06, 2023 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Coherus, Nasdaq: CHRS), today announced data from the ongoing Phase 1b/2 clinical trial of casdozokitug (casdozo), a first-in-class IL-27-targeting antibody, being presented at the 2023 ESMO Immuno-Oncology Congress taking place December 6 – 8, 2023 at Palexpo Exhibition Centre in Geneva, Switzerland. The presentation includes updated data for casdozo monotherapy dose escalation and expansion cohorts and a cohort evaluating treatment with casdozo in combination with the anti-PD-1 antibody pembrolizumab (pembro) in patients with non-small cell lung cancer (NSCLC) who have progressed after 2-4 prior lines of therapy, including chemotherapy and anti-PD-1 agents. Interleukin (IL)-27 is an immunoregulatory cytokine involved in suppressing anti-tumor immune responses and an important new target for cancer treatment. Casdozo is a first-in-class antibody, and the only clinical stage immunomodulatory cytokine antagonist targeting IL-27.

"'Cold' and 'excluded' tumor immune microenvironments are the least likely to respond to checkpoint blockade and present a unique challenge to the field of cancer immunotherapy, and IL-27 production by tumor infiltrating macrophages may be one key mechanism by which tumors exclude key anti-tumor lymphocytes," said Thomas Marron, M.D., Ph.D., Director, Early Phase Trials Unit, The Tisch Cancer Center. "The responses in pre-treated patients who have progressed on PD-1 blockade are extremely encouraging and warrant further investigation both in the relapsed/refractory setting and potentially up-front. The responses we saw in patients with squamous cell carcinoma are particularly intriguing, and further analysis of the tissue and blood of these patients will hopefully reveal biomarkers to further enrich for patients likely to respond to casdozo."

"We are pleased to see that casdozo has demonstrated immune activation and monotherapy anti-tumor activity with an acceptable safety profile in NSCLC. These data continue to support the blocking of IL-27 as a novel strategy to overcome immune suppression in difficult to treat patients with solid tumors," said Rosh Dias Coherus' Chief Medical Officer. "The casdozo and anti PD-1 antibody combination has been well tolerated in this study, and as we continue to advance our own internal next-generation immuno-oncology combinations, we look forward to the results of the novel combination of casdozo and our anti-PD-1 antibody toripalimab-tpzi which will enroll as the final cohort in this study."

Phase 1b/2 clinical trial design
The ongoing first-in-human open-label Phase 1b/2 dose escalation and expansion study of casdozo in advanced solid tumors comprises multiple parts: Part A monotherapy dose escalation (N=29; NSCLC N=5), Part B monotherapy dose expansion in NSCLC (N=40), HCC (N=17), and ccRCC (N=27), Part C combination with pembro in anti PD-(L)1 R/R NSCLC (N=6), HCC (N=7), and RCC (N=3) and Part D combination with toripalimab in anti PD-(L)1 R/R NSCLC (Target N=40). As monotherapy, casdozo demonstrated favorable safety and preliminary anti-tumor activity. Expansion cohorts in NSCLC have evaluated casdozo 10 mg/kg IV q4w as monotherapy and q3w in combination with pembrolizumab in treatment-refractory NSCLC. Part C was halted early due to changes in company objectives, and the Part D cohort evaluating casdozo in combination with toripalimab-tpzi is now enrolling. The primary endpoint is objective response rate (ORR) based on investigator review per RECIST v1.1. Key secondary endpoints include safety and tolerability and additional measures of efficacy (duration of response (DoR) and disease control rate (DCR) based on investigator review per RECIST v1.1).

Phase 1b/2 clinical trial data
As of the cutoff date (September 21, 2023), in response-evaluable patients (n=43) there were two confirmed partial responders (PRs) in PD-L1 negative or low, squamous NSCLC and one durable disease stabilization in adenocarcinoma. All three patients received casdozo monotherapy and had been previously treated with anti-PD-L1 antibodies. Immunohistochemistry (HC) analysis of tissue from one squamous NSCLC patient who experienced a partial response shows features of an immune excluded tumor microenvironment which can indicate anti-tumor response to treatment, as well as prominent IL-27 staining indicative of high target engagement. The overall response rate (ORR) in the subset of patients with squamous NSCLC (n=2/9) was 22% in this data cut. Casdozo continues to demonstrate an acceptable safety profile as monotherapy or in combination with a PD-1 inhibitor (pembro).

Poster presentation details:
Title: *Casdozokitug (casdozo, CHS-388), a first-in-class IL-27 targeting antibody as monotherapy or in combination with pembrolizumab (pembro) in treatment-refractory non-small cell lung cancer (NSCLC)*
Presentation number: #122P
Date and Time: Thursday, December 7, 2023, 12:00 – 13:00 CET
Presenter: Thomas Marron, M.D., Ph.D.
Location: Foyer mezzanine – Palexpo Exhibition Centre, Geneva

Poster presentation data are summarized as follows:

- Casdozokitug has demonstrated immune activation and single agent responses in PD-(L)1 experienced, PD-L1 low NSCLC patients, with an acceptable safety profile alone and in combination with a PD-1 inhibitor (pembro); in squamous NSCLC, two of nine patients had confirmed PRs
- The combination of casdozo + pembrolizumab was well tolerated with a best response of stable disease in the first five response-evaluable NSCLC patients treated
- Results support continued evaluation of casdozo to relieve tumor immune suppression in combination with PD-1 inhibitors and other novel agents in NSCLC
- Phase 2 study of the PD-1 antibody, toripalimab, and casdozo is currently enrolling

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. 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). Coherus anticipates data from the HCC clinical trial in Q1 2024. Casdozokitug has been granted Orphan Drug designation and Fast Track designation for the treatment of refractory hepatocellular carcinoma from the FDA. It is the first IL-27 antibody to enter the clinic.

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' immuno-oncology pipeline 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 is a novel anti-IL-27 antibody currently being evaluated in two on-going clinical studies: a Phase 1/2 study in advanced solid tumors and a Phase 2 study in hepatocellular carcinoma. CHS-114 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, including CHS-006, a TIGIT-targeted antibody, being evaluated in a Phase 1/2 clinical trial in combination with LOQTORZI in patients with advanced solid tumors, and CHS-1000, a preclinical program targeting the novel pathway ILT4.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®, YUSIMRY™ (adalimumab-aqvh), a biosimilar of Humira® and plans to launch LOQTORZI™ (toripalimab-tpzi), a novel next generation PD-1 inhibitor, in the U.S. in January 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 find synergies between its I-O pipeline and its commercial operations; and expectations for the launch date of LOQTORZI.

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 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 September 30, 2023 filed with the Securities and Exchange Commission on November 6, 2023, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission.

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