Coherus Presents Positive Phase 2 Clinical Data on Casdozokitug, a First-in-Class IL-27-Targeted Antibody, at the 2024 ASCO GI Cancers Symposium

– Data demonstrate early activity with casdozokitug/atezolizumab/bevacizumab; 38% objective response rate including three complete responses –

– Data support casdozo as a promising novel immuno-oncology agent with clinical activity in liver cancer that may be associated with IL-27 pathway biomarkers –

– Data support continued evaluation of casdozo with VEGF and PD-(L)1 blockade in HCC, including further clinical development to evaluate casdozokitug/toripalimab/bevacizumab –

REDWOOD CITY, Calif., Jan. 18, 2024 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Coherus, Nasdaq: CHRS), today announced data from the lead-in portion of the Phase 2 clinical trial evaluating casdozokitug (casdozo), a selective and potent IL-27-targeting antibody, in combination with atezolizumab (atezo) and bevacizumab (bev) in treatment naïve patients with unresectable locally advanced or metastatic hepatocellular carcinoma (uHCC). These data are being presented at the 2024 ASCO Gastrointestinal Cancers Symposium taking place January 18-20, 2024 at Moscone West in San Francisco, California. 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.

“Doublet immunotherapy combinations for the treatment of liver cancer have improved outcomes for patients for whom surgery is not an option or whose cancer has spread. However, not all patients respond to current therapy and novel treatment options that can further improve survival without added toxicity are needed,” said Daneng Li, M.D., Associate Professor in the Department of Medical Oncology & Therapeutics Research and Co-Director, Liver Cancer Collaborative Program, City of Hope Comprehensive Cancer Center. “The addition of casdozo to standard of care is encouraging and supports further evaluation of cazdozo, and its novel anti-IL-27 mechanism, as part of triplet therapy in HCC. Additionally, each person with advanced HCC is unique with respect to their tumor, co-morbidities and other factors – the biomarker data showing an association of IL-27 biology and response to casdozo is particularly interesting and the potential to identify biomarkers of response would be an important benefit to patients with liver cancer.”

“These impressive early clinical and immune activation data for casdozo in HCC demonstrating an ORR of 38%, including 3 complete responses, and a favorable safety profile add to the growing body of data supporting IL-27 as a promising novel target in combination therapy for advanced solid tumors,” said Rosh Dias, M.D., Coherus’ Chief Medical Officer. “We now have data across several tumor types for casdozo demonstrating clinical activity. Our comprehensive clinical development program of ongoing and planned clinical trials including casdozokitug in combination with our anti-PD-1 antibody backbone of toripalimab-tpzi, will further advance our internal next-generation immuno-oncology combinations focused on overcoming immune suppression in the tumor microenvironment with the goal of extending survival and improving outcomes for patients.”

Lead-in portion of Phase 2 clinical trial design
The open-label lead-in portion of the Phase 2 clinical trial evaluated casdozo in combination with atezo and bev in 30 patients with treatment-naïve uHCC. Patients received casdozo 10 mg/kg IV q3w, in combination with atezo (1200 mg) and bev (15 mg/kg). The primary endpoint of the lead-in portion of the study was safety and tolerability. Key secondary endpoints included progression-free survival (PFS) and overall response rate (ORR) based on investigator review per RECIST v1.1 (primary) and mRECIST (secondary), as well as disease control rate (DCR). Further [Phase 2] clinical development of cazdozo in HCC is planned to evaluate casdozo/toripalimab (anti-PD-1 antibody)/bev.

Lead-in portion of Phase 2 clinical trial data
As of the data cutoff date (November 9, 2023):
Triplet blockade of the IL-27, PD-(L)1 and VEGF pathways with casdozo/atezo/bev has an acceptable safety profile to date with promising antitumor activity in IO naïve HCC.

- Triplet combination treatment was well tolerated with side effect profile consistent with known adverse event (AE) profiles of atezo/bev.
- Encouraging early activity with casdozo/atezo/bev:
  - RECIST v1.1: ORR of 38% (n=29) with 11 durable objective responses including 3 complete responses and 8 partial responses (1 unconfirmed); median progression-free survival of 8.1 months and disease control rate of 58.6%.
  - mRECIST: ORR of 43% (n=28) with 12 durable objective responses including 3 complete responses and 9 partial responses (1 unconfirmed); median progression-free survival not reached and disease control rate of 60.7%.
- Further analyses of samples from patients who responded to treatment (small n) indicate preliminary association between response and biomarkers of IL-27.

These results support continued evaluation of casdozo with VEGF and PD-(L)1 blockade in HCC. Coherus plans to evaluate the combination of casdozo/toripalimab-tpzi(Coherus’ anti-PD-1 antibody)/bev in future clinical trials.

Poster presentation details:
Title: *Results from a phase 2 study of triplet blockade of the IL-27, PD-(L)1, and VegF pathways with casdozokitug (casdozo, CHS-388) in combination with atezolizumab (atezo) and bevacizumab (bev) in patients with unresectable, locally advanced or metastatic hepatocellular carcinoma (uHCC)*
Poster Board number: B15
Abstract number: 470
Date and Time: Friday, January 19, 2024, 12:30 – 2:00 pm PT
Presenter: Daneng Li, MD
Location: Level 1, West Hall, Moscone West

About Casdozokitug

Casdozokitug 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). An ongoing trial is studying combinations with PD-(L)1 pathway blockade in NSCLC and a planned clnical trial will study the triplet combination of IL-27, PD-(L)1 and VEGF pathway blockade in hepatocellular carcinoma (HCC). 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. CHS-1000 is a preclinical candidate targeting immune-suppressive mechanisms via the novel pathway ILT4 with an IND filing planned in the first half of 2024.

Coherus markets LOQTORZI™ (toripalimab-tpzi), a novel next generation PD-1 inhibitor, 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 find synergies between its I-O pipeline and its commercial operations; expectations for the timing of an IND filing for CHS-1000; statements that the Coherus immuno-oncology pipeline will extend survival and enhance outcomes for cancer 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 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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