Coherus Presents Final Phase 2 Clinical Casdozokitug Combination Data in Patients with Metastatic Hepatocellular Carcinoma at ASCO-GI 2025

– Casdozokitug, in combination with atezolizumab/bevacizumab, final data demonstrate durability of response and improvement in depth of response including a 17.2% complete response rate –

– Antitumor activity was observed across both viral and non-viral etiologies –

– Data support continued evaluation of casdozokitug with VEGF and PD-(L)1 blockade in HCC –

- Randomized Phase 2 trial evaluating casdozokitug/bevacizumab/toripalimab now open for enrollment –

REDWOOD CITY, Calif., Jan. 22, 2025 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Coherus, NASDAQ: CHRS), today announced final data from its Phase 2 open label clinical trial evaluating casdozokitug (casdozo), a selective and potent Interleukin (IL)-27-targeting antibody, in combination with atezolizumab (atezo) and bevacizumab (bev) in treatment naïve patients with unresectable locally advanced or metastatic hepatocellular carcinoma (HCC). These data are being presented at the 2025 ASCO Gastrointestinal Cancers Symposium taking place January 23-25, 2025, in San Francisco, California.

These data showed an overall response rate of 38% compared to initially announced 27%[1], and complete responses (CR) per RECIST v1.1 increased to 17.2% compared to previously announced 10.3%[2] and initial assessment of 0%[1], demonstrating both an increase in ORR and a deepening of responses compared to previous datasets. Importantly, responses were seen in viral and nonviral disease, and toxicity was consistent with the known safety profiles of atezolizumab and bevacizumab, with no new safety signals identified.

These data support continued evaluation of casdozo with other therapies, including a trial of casdozo/toripalimab (tori)/bev in HCC, which Coherus has now opened for enrollment. Casdozo is a first-in-class antibody, and the only clinical-stage immunomodulatory cytokine antagonist targeting IL-27, an immunoregulatory cytokine involved in suppressing anti-tumor immune responses and an important new target for cancer treatment.

“The casdozo data in HCC demonstrate translation of the preclinical data in liver cancer to first-line HCC cancer patients with efficacy and a favorable safety profile. These data support the ongoing development of IL-27 as a promising novel target for advanced solid tumors,” said Rosh Dias, M.D., Coherus’ Chief Medical Officer. “We recently opened enrollment for our randomized, controlled, multinational Phase 2 trial of casdozo in combination with toripalimab, our anti-PD-1 antibody, plus bev. The combination of tori plus bev has demonstrated promising Phase 3 results in HCC[3], and we believe the addition of casdozo may further enhance anti-tumor effects and advance our next-generation immuno-oncology combinations focused on overcoming immune suppression in the tumor microenvironment.”

“The treatment landscape for liver cancer, particularly for patients who are not eligible for surgery or who are metastatic, has improved in recent years thanks to immunotherapy combinations. However, there is still a clear unmet need for novel treatment options that can further improve survival without added toxicity,” 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. “These final casdozo data continue to be encouraging and compare very favorably in the current treatment landscape, and speak to the potential for its novel anti-IL-27 mechanism to address these substantial unmet needs.”

Results from Phase 2 trial evaluating casdozo/atezo/bev combination in HCC

This open-label Phase 2 clinical trial evaluated casdozo in combination with atezo and bev in 30 treatment-naïve patients with unresectable locally advanced or metastatic HCC. Patients received casdozokitug 10 mg/kg IV q3w in combination with atezolizumab (1200 mg) and bevacizumab (15 mg/kg). The primary endpoint was safety and tolerability. Key secondary endpoints included PFS and ORR based on investigator review per RECIST v1.1 (primary) and mRECIST (secondary), as well as disease control rate (DCR).

As of the data cutoff date of September 4, 2024:

Triplet blockade of the IL-27, PD-(L)1 and VEGF inhibitors with casdozo/atezo/bev demonstrated an acceptable safety profile with promising antitumor activity in immunotherapy naïve HCC.

- Triplet combination treatment was well tolerated with a 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 objective responses, including 5 complete responses and 6 confirmed partial responses; median progression-free survival (PFS) of 8.1 months and disease control rate of 58.6%.
  - mRECIST: ORR of 43% (n=28) with 12 objective responses, including 5 complete responses and 7 confirmed partial responses; median PFS of 8.4 months and disease control rate of 60.7%.
  - Biomarker data show peripheral inhibition of IL-27 signaling and immune activation in NK and T cells following treatment, consistent with the casdozo preclinical data and mechanism of action.

These results support continued evaluation of casdozo with VEGF and PD-(L)1 blockade in HCC.

Recent Launch of New Phase 2 trial evaluating casdozo in combination with bev and toripalimab

Coherus has initiated a new randomized Phase 2 study (NCT06679985) evaluating casdozo, in combination with bev and tori, Coherus’ next-generation anti-PD-1 monoclonal antibody, in participants with unresectable locally advanced or metastatic HCC. This randomized, parallel, open-label Phase 2 study is designed to evaluate the safety, efficacy, and Project Optimus[4] dosing of the triplet combination. The study is expected to

enroll up to 72 patients, who will be randomized to receive one of two biologically active doses of casdozo with tori plus bev or tori plus bev without casdozo.

ASCO-GI 2025 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 and bevacizumab in patients with unresectable, locally advanced or metastatic hepatocellular carcinoma (uHCC)
Lead Author: Daneng Li, *City of Hope National Comprehensive Cancer Center*
Abstract 605: Poster Board #D6
Poster Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract
Date and Time: Friday, January 24, 2025; 11:30am – 1:00pm PT

About Hepatocellular Carcinoma

Hepatobiliary cancers include a spectrum of invasive carcinomas arising in the liver (hepatocellular carcinoma; HCC), gall bladder, and bile ducts (collectively called biliary tract cancers). The most common type of primary liver cancer in adults is HCC (accounting for ~90%), which is the third leading cause of cancer-related deaths worldwide. According to the NCI Surveillance, Epidemiology and End Results Program (SEER), there will be an estimated 41,630 new cases and 29,840 deaths from liver and intrahepatic bile duct cancer in the US in 2024.[5] The U.S. 5-year relative survival rate for liver and intrahepatic bile duct cancer is 21.7%.[5] The liver cancer treatment pattern has changed in recent years with the emergence of immunotherapy combinations and will continue to evolve as more treatment options become available for these highly lethal cancers.

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 clinical trial will study the triplet combination of IL-27, PD-(L)1, and VEGF pathway blockade in 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 is expected to 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 antitumor immunologic response and enhance outcomes for patients with cancer. Casdozokitug is a novel IL-27 antagonistic antibody currently being evaluated in two ongoing 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, cytolytic anti-CCR8 antibody currently in a Phase 1 study in patients with advanced solid tumors, including HNSCC. CHS-1000 is a novel humanized Fc-modified IgG1 monoclonal antibody specifically targeting ILT4 (LILRB2). An IND for CHS-1000 was allowed to proceed by the FDA in the second quarter of 2024 and proceeding to the first-in-human clinical study is subject to further evaluation in Coherus' portfolio prioritization process.

Coherus markets LOQTORZI® (toripalimab-tpzi), a novel next-generation PD-1 inhibitor, and UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta. In December 2024, Coherus announced the planned divestiture of its UDENYCA franchise. The transaction is expected to close by the end of the first quarter of 2025.

Neulasta® is a registered trademark of Amgen, Inc.

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' expectations about identifying synergies between its I-O pipeline and its commercial operations; statements about new cases and deaths from liver cancer and intrahepatic bile duct cancer in the US; estimates of future enrollment in Coherus' clinical studies; Coherus' expectations that its clinical pipeline candidates may extend patient survival and enhance anti-tumor effects; and statements about the closing conditions to consummate the proposed transaction for the divestiture of Coherus' UDENYCA franchise being satisfied at all or in the estimated time.

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 Coherus' existing and potential collaboration partners; risks of Coherus' reliance on third-parties; the risks and uncertainties related to manufacturing and supply of Coherus' products, the risks and uncertainties of the regulatory approval process, including the speed of regulatory review and the timing of Coherus' regulatory filings; uncertainties as to the timing for completion of the proposed transaction; uncertainties as to Coherus' ability to obtain the approval of its shareholders required to consummate the proposed transaction for the divestiture of UDENYCA; the possibility that competing offers will be made by third parties; the occurrence of any event, change or other circumstance that may give rise to a right of one or both parties to terminate the agreement to divest UDENYCA; the possibility that the proposed transaction for the divestiture of UDENYCA may not be completed in the time frame expected by Coherus or at all, including due to the possibility that a governmental entity may prohibit, delay, or refuse to grant approval, if required, for the consummation of the proposed transaction to divest UDENYCA (or only grant approval subject to adverse conditions or limitations). All forward-looking statements contained in this press release speak only as of the date of this press release. 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. 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, 2024 filed with the Securities and Exchange Commission (SEC) on November 6, 2024, including the section therein captioned "Risk Factors" and in other documents Coherus files with the SEC including the preliminary proxy statement of Coherus relating to the proposed transaction for the divestiture of UDENYCA filed with the SEC on January 14, 2025 and, when available, the definitive proxy statement of Coherus relating to the proposed transaction for the divestiture of UDENYCA.

companies or its licensors or joint venture partners unless otherwise noted. Trademarks and trade names of other companies appearing in this press release are, to the knowledge of Coherus, the property of their respective owners.

References

[1] Coherus to Acquire Surface Oncology (2023, June 16) [Press Release]

[2]Daneng Li et al., *JCO* 42, 470-470(2024).

[3]Yinghong S, et al. Oral presentation at: CSCO 2024; September 27, 2024; Xiamen, China.

[4]Project Optimus: Reforming the dose optimization and dose selection paradigm in oncology

[5]National Cancer Institute Cancer Stat Facts: Liver and Intrahepatic Bile Duct Cancer; retrieved December 17, 2024, from https://seer.cancer.gov/statfacts/html/livibd.html

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