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

Dec 18, 2024

- Randomized Phase 2 study initiated evaluating the combination of casdozokitug, toripalimab and bevacizumab in patients with liver cancer -

REDWOOD CITY, Calif., Dec. 18, 2024 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus," NASDAQ: CHRS) today announced that an abstract highlighting final clinical and biomarker data from its Phase 2 clinical trial evaluating casdozokitug (casdozo), a selective and potent IL-27-antagonistic antibody, in combination with atezolizumab (atezo) and bevacizumab (bev) in treatment naïve patients with unresectable locally advanced or metastatic hepatocellular carcinoma (HCC), has been selected for a poster presentation at the upcoming 2025 ASCO GI Annual Meeting, being held January 23-25, 2025, in San Fransisco, CA.

"Casdozo is a first-in-class antibody, and in oncology, is the first IL-27 cytokine antagonist to demonstrate monotherapy responses and immune activation with a safety profile that lends itself to combination," said Rosh Dias, M.D., Coherus' Chief Medical Officer. "We look forward to sharing the final data from this Phase 2 combination study of casdozo with standard of care with the medical community at the upcoming 2025 ASCO-GI annual meeting. We now have data across several tumor types for casdozo demonstrating clinical activity. We are particularly excited about HCC given the strong preclinical package for targeting IL-27 in liver cancer and now translation to the clinic."

Coherus has initiated a new randomized Phase 2 study (NCT06679985) evaluating casdozo, in combination with bevacizumab and toripalimab, Coherus' next-generation anti-PD-1 monoclonal antibody, in participants with first-line HCC. This randomized, parallel, open-label Phase 2 study is designed to evaluate the safety, efficacy, and Project Optimus[1] 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 toripalimab plus bevacizumab or toripalimab plus bevacizumab without casdozo.

"Advancing casdozo development in first-line HCC with a randomized Phase 2 combination study marks a significant milestone in our strategic path to progress our clinical pipeline, which is focused on overcoming immune suppression in the tumor microenvironment to extend survival and improve outcomes for patients and pursuing new indications for toripalimab in the U.S.," continued Dr. Dias. "Casdozo has shown encouraging responses in the first line setting when added to the existing standard of care, atezolizumab and bevacizumab, and we're excited to build upon these data with this new Phase 2 study evaluating casdozo in combination with toripalimab and bevacizumab."

In the Phase 3 HEPATORCH study, conducted by Junshi Biosciences, patients with advanced HCC treated with toripalimab combined with bevacizumab as a first-line therapy showed significantly better clinical efficacy than sorafenib monotherapy.[2] HEPATORCH patients showed an objective response rate of 25.3% versus 6.1% in the sorafenib group, a median progression-free survival of 5.8 months, and a median overall survival of 20 months, compared to 4 and 14.5 months, respectively, for the sorafenib group.[3] Toripalimab in combination with bevacizumab was well tolerated, with a toxicity profile consistent with the known toxicity profile of each monotherapy, with no new safety signals identified.[3] The results of the HEPATORCH study support the clinical study of toripalimab in combination with bevacizumab as a new first-line treatment option for advanced HCC which, along with the results from the Phase 2 casdozo study reported to date, support pursuing a triple combination of casdozo with toripalimab plus bevacizumab in patients with advanced or metastatic HCC.

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 Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract
Date and Time: Friday, January 24, 2025; 11:30 a.m. – 1:00 p.m. PT

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.[4] The U.S. 5-year relative survival rate for liver and intrahepatic bile duct cancer is 21.7%.[4] 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 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 toripalimab and 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, particularly patients underserved by current immunotherapy treatments. Casdozokitug is a novel IL-27 antagonistic antibody 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 our 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 that it entered into an agreement for the divestiture of the UDENYCA franchise. The proposed

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 and its I-O pipeline and toripalimab; future enrollment estimates for Coherus' clinical studies; Coherus' expectations that it will be able to demonstrate that its clinical pipeline candidates can extend patient survival; and the ability to satisfy the closing conditions to consummate the proposed transaction for the divestiture of the UDENYCA franchise 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 the Company's 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 the Company 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, the Company 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 on November 6, 2024, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission including, when available, the proxy statement of the Company relating to the proposed transaction for the divestiture of UDENYCA.

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Coherus Contact Information:
For Investors:
Jodi Sievers
VP, Investor Relations & Corporate Communications
IR@coherus.com

For Media:
Argot Partners
(212) 600-1902
coherus@argotpartners.com

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

[2]Shanghai Junshi Biosciences Co., Ltd (2024, June 11) *Junshi Biosciences Announces Phase 3 Study of Toripalimab Combined with Bevacizumab for the First-line Treatment of Advanced Hepatocellular Carcinoma Meets Primary Endpoint*

[3]FAN, J. (2024) *HEPATORCH: A randomized, open-label, multicenter, phase III clinical study of the safety and efficacy of toripalimab combined with bevacizumab versus sorafenib as first-line treatment for advanced hepatocellular carcinoma* presented at the 2024 Annual Meeting of Chinese Society of Clinical Oncology

[4]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

Source: Coherus BioSciences, Inc.