Source: *Coherus BioSciences, Inc.*

May 08, 2024 09:00 ET

Coherus Announces Clinical Collaboration with the Cancer Research Institute for a Novel Combination Evaluating LOQTORZI® (toripalimab-tpzi) with ENB Therapeutics' ENB-003 for the Treatment of Ovarian Cancer

REDWOOD CITY, Calif., May 08, 2024 (GLOBE NEWSWIRE) -- **Coherus BioSciences, Inc.** (Coherus; Nasdaq: CHRS) today announced that the Cancer Research Institute (CRI) and its Immunotherapy Platform Study in Platinum-Resistant High-Grade Serous Ovarian Cancer (IPROC) Drug Selection Committee (DSC) have selected LOQTORZI (toripalimab-tpzi), anti-PD-1 antibody, to explore in combination with ENB-003, a first-in-class small molecule inhibitor of endothelin B receptor (ETBR), for the treatment of drug-resistant cancers in the iPROC platform study. Endothelin B receptor is implicated in tumorigenesis and tumor immune suppression for several solid tumors, including melanoma, ovarian, and pancreatic cancers.

“The iPROC DSC is pleased to have access to this next-generation PD-1 inhibitor and advance this combination supported by preclinical and clinical data in this study in ovarian cancer,” said John Stagg, Ph.D., Professor, Faculty of Pharmacy at the University of Montreal and Principal Investigator, Centre Hospitalier de l’Université de Montréal (CHUM) and its affiliated Cancer Institute of Montreal.

Dr. Stagg continued, “The iPROC study DSC brings together a group of scientific experts within the CRI community to select promising combinations and rapidly advance them to clinical trials. Importantly, the DSC is not confined by a pipeline but looks to work with companies with drugs that have a strong data package. For this multiparty platform study to succeed, it requires science-driven, highly collaborative, and engaged companies. Coherus and ENB Therapeutics are two such partners, and we are excited to advance this clinical study.”

“CRI is an established and preeminent organization leading immunotherapy discovery and advancement through its global network of scientific experts, and we are excited that the CRI network has selected LOQTORZI for this study to gain more insight into the potential clinical benefit that LOQTORZI might have when combined with novel mechanisms such as ENB Therapeutics’ ETBR blocker, particularly in this underserved patient population,” said Rosh Dias, M.D., Chief Medical Officer at Coherus.

“There is a large body of clinical evidence for LOQTORZI, including positive phase 3 studies published in top-tier scientific journals, showing efficacy and safety in multiple tumor types,” said Jay Campbell, Managing Director, Clinical Accelerator and Venture Fund at CRI. “This level of scientific evidence is what we are looking for when selecting immunotherapies to bring into our network, with the goal of advancing clinically meaningful solutions to patients. We are grateful to have the opportunity to collaborate with Coherus and ENB Therapeutics on this study and excited to be working with them on this novel combination that we hope will lead to improved outcomes in these patient populations.”

Dr. Sumayah Jamal, CEO of ENB Therapeutics, added, “We are honored to be collaborating with CRI and Coherus to further accelerate the development of innovative immunotherapy solutions and expand the pool of patients benefitting from this approach to harness the immune system to fight cancer.”

Under the terms of a clinical supply agreement with the Cancer Research Institute (CRI), Coherus will supply toripalimab-tpzi for combination treatment with ENB-003 to be investigated in the

iPROC platform study.

About the IPROC Platform Trial
The IPROC clinical trial uses an adaptive platform study design that utilizes a single master protocol to evaluate multiple immunotherapy combinations. This allows multiple treatments to be evaluated in different groups of patients, or cohorts, from the same patient population. Such a study design offers flexibility in that different treatments can be evaluated in different cohorts, treatment regimens can be modified between cohorts, and treatment selection criteria can be customized for a specific cohort. The trial, titled *Immunotherapy Platform Study in Platinum-Resistant High-Grade Serous Ovarian Cancer (IPROC)* (NCT04918186), has two ongoing cohorts.

About LOQTORZI (toripalimab-tpzi)
LOQTORZI is an anti-PD-1 monoclonal antibody that blocks PD-L1 binding to the PD-1 receptor at a unique site with high affinity and activates anti-tumor immunity. LOQTORZI is indicated in the United States in combination with cisplatin and gemcitabine for first-line treatment of adults with metastatic or recurrent locally advanced nasopharyngeal carcinoma (NPC) and as a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after platinum-containing chemotherapy. For more information about LOQTORZI, including the U.S. Prescribing Information and important safety information, please visit www.loqtorzi.com.

About ENB-003
ENB-003, a small-molecule drug candidate targeting the ETBR, is expressed in solid tumors and plays a role in tumorigenesis and immune evasion. ETBR, a G-protein-coupled receptor, is overexpressed in a variety of tumor cell types and plays a key role in tumor cell proliferation, invasion, epithelial-mesenchymal transition (EMT), and angiogenesis. It also plays a role in tumor immunosuppression and blocks T-cell trafficking.

As reported in November 2023, preliminary results from the ENBOLDEN-101 demonstrated that ENB-003 in combination with KEYTRUDA® (pembrolizumab) demonstrated encouraging objective responses, disease control, and progression-free survival in patients with metastatic platinum refractory/resistant ovarian cancer (PROC).

About the Cancer Research Institute
The Cancer Research Institute, established in 1953, is the preeminent U.S. nonprofit organization dedicated to saving more lives by fueling the discovery and development of powerful immunotherapies for all cancers. Guided by a world-renowned Scientific Advisory Council that includes four Nobel laureates and 35 members of the National Academy of Sciences, CRI has invested over $517 million in support of research conducted by immunologists and tumor immunologists at the world's leading medical centers and universities and has contributed to many of the key scientific advances that demonstrate the potential for immunotherapy to change the face of cancer treatment. Learn more at cancerresearch.org.

About Coherus BioSciences
Coherus is a commercial-stage biopharmaceutical company focused on researching, developing, and commercializing innovative cancer treatments. Coherus is developing an innovative immuno-oncology pipeline that is expected to synergize 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. CHS-1000, a novel ILT4-targeted antibody, is a preclinical candidate targeting immune-suppressive mechanisms via the pathway ILT4.

Coherus markets LOQTORZI® (toripalimab-tpzi), a novel next-generation PD-1 inhibitor, UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, and YUSIMRY® (adalimumab-aqvh), a biosimilar of Humira®.

About ENB Therapeutics
ENB Therapeutics is a clinical-stage biopharmaceutical company developing a novel class of medicines, ETBR inhibitors, to overcome resistance to CAR-T in solid tumors and immune-based therapies such as immune checkpoint inhibitors. ETBR causes uncontrolled cancer growth, drives

cancers to spread through the body, and prevents the immune system from detecting and killing cancer cells. ENB's lead product candidate, ENB-003, specifically blocks the ETBR and can potentially drive the efficacy of CAR-T and anti-PD1 therapies in solid tumors. ENB-003 is being investigated in an ongoing Phase 1/2 clinical trial in collaboration with Merck.

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 identify synergies between its I-O pipeline and its commercial capabilities; Coherus' expected initiating clinical trials for CHS-1000; Coherus' expectations to be able to advance its candidates through clinical trials; and Coherus' expectations that its immunotherapy candidates will enhance outcomes for patients with cancer.

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 preclinical and clinical drug development process; 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 and the timing of Coherus' regulatory filings; the risks of competition; the risk that Coherus is unable to complete commercial transactions; 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' Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the Securities and Exchange Commission on March 15, 2024, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission.

Coherus Contact Information:
For Investors:
Jami Taylor
Head of Investor Relations
IR@coherus.com

For Media:
Jodi Sievers
VP, Corporate Communications
media@coherus.com