FDA Issues Complete Response Letter (CRL) for UDENYCA® ONBODY™ Biologics License Application Solely Due to an Ongoing Review of Inspection Findings at a Third-Party Filler; Coherus Also Announces Completion of Toripalimab FDA Inspections

Sep 25, 2023

– No issues with clinical efficacy or safety, trial design, labeling, drug substance manufacturing, or device design or manufacturing were identified in the UDENYCA® ONBODY ™ CRL –

– No additional UDENYCA® ONBODY ™ clinical data or trials have been requested by the FDA –

– Toripalimab inspections completed –

REDWOOD CITY, Calif., Sept. 25, 2023 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus”, NASDAQ: CHRS), a commercial-stage biopharmaceutical company focused on the research, development, and commercialization of innovative immunotherapies to treat cancer, announced today that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) supplement for UDENYCA® ONBODY™, the company's on-body injector (OBI) presentation of UDENYCA® (pegfilgrastim-cbqv), solely due to an ongoing review of inspection findings at a third-party filler. The CRL did not identify any issues with the UDENYCA® ONBODY™ clinical efficacy or safety, trial design, labeling, drug substance manufacturing, or device design or manufacturing, and no additional data or trials have been requested. Coherus is committed to working closely with the FDA and the third-party filler to bring UDENYCA® ONBODY™ to cancer patients requiring pegfilgrastim treatment as quickly as possible.

Coherus also announced completion of FDA’s toripalimab inspections
Coherus also announced today that the FDA has completed the clinical study site inspections of three clinical sites in China that enrolled subjects in the two pivotal clinical trials supporting the toripalimab BLA for the treatment of metastatic or recurrent nasopharyngeal carcinoma (NPC) as first-line treatment or as second or greater line treatment. Only one site received an FDA Form 483, with one observation noted. Coherus believes the observation is readily addressable. Coherus continues to anticipate potential approval for toripalimab by year end 2023.

“We are pleased the FDA has completed the review elements for the OBI and toripalimab applications,” said Dr. Theresa LaVallee, Coherus Chief Development Officer. “We will work with the third-party filler to address the issues and resubmit the UDENYCA® ONBODY™ application as quickly as possible. Having completed all the required review elements of the toripalimab BLA, we will continue to work collaboratively with the FDA to bring toripalimab, with its substantial improvement in survival compared to chemotherapy, to NPC patients. NPC is a rare cancer with high unmet medical need that has no drugs approved for treatment of this disease in the U.S.”

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.

Through an in-licensing agreement with Shanghai Junshi Biosciences Ltd., Coherus is developing toripalimab, an anti-PD-1 antibody, in the United States and Canada. A BLA for toripalimab for the treatment of nasopharyngeal carcinoma is under review by the FDA. Toripalimab is approved in China for the treatment of melanoma, urothelial cancer, esophageal squamous cell carcinoma, nasopharyngeal carcinoma and non-small cell lung cancer.

Through its acquisition of Surface Oncology, Coherus’ immuno-oncology pipeline now 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 (SRF388) is a novel anti-IL-27 antibody currently being evaluated in Phase 1/2 clinical trials in lung and liver cancer. CHS-114 (SRF114) is a highly selective, competitively positioned anti-CCR8 antibody currently in a Phase 1/2 study as a monotherapy in patients with advanced solid tumors. There are also two out-licensed partnership programs to advance its next-generation cancer therapies.

Coherus’ earlier-stage immuno-oncology pipeline targets immune-suppressive mechanisms in the tumor microenvironment, including CHS-006, a TIGIT-targeted antibody, being evaluated in a Phase 1/2 clinical trial in combination with toripalimab 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®, 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 whether Coherus’ innovative immuno-oncology pipeline will be synergistic with its proven commercial capabilities in oncology and whether the FDA’s Form-483 observations will be readily addressable and have no impact on approval timing .

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, risks related to our existing and potential collaboration partners, the risks and uncertainties inherent in the clinical drug development process; risks relating to competition; risks of the drug development position of Coherus’ competitors; 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; 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 June

30, 2023, filed with the Securities and Exchange Commission on August 2, 2023, including the section therein captioned “Risk Factors” and in other documents that Coherus files with the Securities and Exchange Commission.

Coherus Contact Information:
For Investors:
Marek Ciszewski, J.D., SVP Investor Relations
IR@coherus.com

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

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