Coherus Announces Resubmission of Biologics License Application (BLA) Supplement for UDENYCA® ONBODY™

– Resubmission follows the satisfactory resolution of the FDA's review of inspection findings at the third-party filler –

REDWOOD CITY, Calif., Oct. 05, 2023 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Coherus, NASDAQ: CHRS) today announced the Company has resubmitted the Biologics License Application (BLA) Supplement for UDENYCA® ONBODY™, the company's on-body injector presentation of UDENYCA® (pegfilgrastim-cbqv), to the U.S. Food and Drug Administration (FDA) for review.

The resubmission of the UDENYCA® ONBODY™ BLA Supplement follows the completion and satisfactory resolution of the FDA's review of inspection findings at a third-party filler, which was the only issue identified in the Complete Response Letter (CRL) the FDA issued on September 21, 2023. 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 to bring UDENYCA® ONBODY™ to cancer patients requiring pegfilgrastim treatment as quickly as possible.

"We are pleased that resolution of the FDA's inspection findings has enabled our rapid resubmission of the UDENYCA® ONBODY™ BLA supplement. As the CRL identified no other issues with the BLA supplement, we look forward to working closely with the agency to complete the review of the UDENYCA® ONBODY™ application in a timely manner and anticipate potential approval later this year," saidTheresa LaVallee, Chief Development Officer of Coherus.

"Coherus appreciates the great collaboration with our third-party manufacturer and the swift and comprehensive actions taken to address the inspectional issues raised by the agency. We are all focused on bringing this excellent product to patients as quickly as possible," said Rich Hameister, Chief Technical Officer at Coherus.

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 recent acquisition of Surface Oncology, Inc., 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 (formerly SRF388) is a novel anti-IL-27 antibody currently being evaluated in Phase 1/2 clinical trials in lung and liver cancer. CHS-114 (formerly 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' immuno-oncology pipeline will have synergies with its commercial capabilities in oncology; expectations about competitive positioning of Coherus' product candidates; and expectations about the timing or ability for Coherus to achieve approval for any of its product candidates.

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 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.

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