Coherus Announces FDA Approval of UDENYCA ONBODY™, a Novel and Proprietary State-of-the-Art Delivery System for pegfilgrastim-cbqv

– Innovative design enables five-minute pegfilgrastim delivery time –

– Unique, automatic, retractable needle mechanism engineered to maximize safety and comfort for cancer patients receiving pegfilgrastim –

REDWOOD CITY, Calif., Dec. 26, 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, today announced that the U.S. Food and Drug Administration (FDA) approved UDENYCA ONBODY™, the company's on-body injector (OBI) presentation of UDENYCA® (pegfilgrastim-cbqv), a pegfilgrastim biosimilar administered the day after chemotherapy to decrease the incidence of infection as manifested by febrile neutropenia.

“The on-body injector for UDENYCA is the result of years of significant investment in research and development to bring forward a novel and proprietary device that provides patients with an automatic delivery option for their medication,” said Denny Lanfear, CEO of Coherus. “Cancer patients and their physicians will now be able to choose the UDENYCA administration presentation that best fits their individual needs: a prefilled syringe, our autoinjector, or this on-body injector.”

“Our market studies showed a significant demand for a novel on-body pegfilgrastim delivery device tailored to specific patient needs. We expect that UDENYCA ONBODY’s five-minute injection time and innovative retractable needle mechanism will be well received by cancer patients, their caregivers, and doctors,” said Paul Reider, Coherus’ Chief Commercial Officer.

“Our state-of-the-art UDENYCA ONBODY device is unlike other approaches in that it is not adapted or repurposed from other medical uses,” said Rich Hameister, Coherus’ Chief Technical Officer. “This is a clean sheet, grounds-up, *de novo* approach designed for pegfilgrastim administration that applies proprietary technology and user insights to produce a reliable and highly intuitive patient experience.”

UDENYCA ONBODY was designed with patients in mind; key features include an indicator and status light and auditive signal that help patients confirm the dose has been administered and a strong and well-tolerated adhesive. After the dose is administered, the needle automatically retracts, which reduces the risk of needlestick injury.

The approval of UDENYCA ONBODY was supported by a comprehensive analytical and clinical data package, including pharmacokinetic (PK) and pharmacodynamic (PD) bioequivalence data as well as adhesive performance and tolerability data.

Commercial availability of UDENYCA ONBODY is planned for the first quarter of 2024.

About UDENYCA

UDENYCA® is the only pegfilgrastim brand approved in the United States available in three administration options—prefilled syringe (PFS), autoinjector (AI) and OBI—providing patients and healthcare providers with choice, control, and convenience. Since its launch in 2019, over 300,000 patients have been treated with UDENYCA.

INDICATION

UDENYCA® is a leukocyte growth factor indicated to:

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

Limitations of Use: UDENYCA® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: Patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products. Reactions have included anaphylaxis.

WARNINGS AND PRECAUTIONS:

- Fatal splenic rupture: Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.
- Acute respiratory distress syndrome (ARDS): Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue UDENYCA® in patients with ARDS.
- Serious allergic reactions, including anaphylaxis: The majority of reported events occurred upon initial exposure. Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue UDENYCA® in patients with serious allergic reactions.
- Allergies to Acrylics: The on-body injector (OBI) for UDENYCA uses acrylic adhesive. For patients who have reactions to acrylic adhesives, use of this product may result in a significant reaction.
- Sickle cell crises: Severe and sometimes fatal crises have occurred. Discontinue UDENYCA® if sickle cell crisis occurs.
- Glomerulonephritis: The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and

renal biopsy. Generally, events resolved after dose reduction or discontinuation. Evaluate and consider dose-reduction or interruption of UDENYCA® if causality is likely.

- Leukocytosis: White blood cell (WBC) counts of 100 x 109/L or greater have been observed in patients receiving pegfilgrastim products. Monitoring of complete blood count (CBC) during UDENYCA® therapy is recommended.
- Thrombocytopenia: Thrombocytopenia has been reported in patients receiving pegfilgrastim. Monitor platelet counts.
- Capillary Leak Syndrome: Has been reported after G-CSF administration, including pegfilgrastim products, and is characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. If symptoms develop, closely monitor and give standard symptomatic treatment, which may include a need for intensive care.
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells: The possibility that pegfilgrastim products act as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim products are not approved, cannot be excluded.
- Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer: MDS and AML have been associated with the use of pegfilgrastim in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for sign and symptoms of MDS/AML in these settings.
- Potential Device failures: Missed or partial doses have been reported for products administered via on-body injectors due to the device not performing as intended. In the event of a missed or partial dose, patients may be at increased risk of events such as neutropenia, febrile neutropenia and/or infection than if the dose had been correctly delivered. Instruct patients using the OBI to notify their healthcare professional immediately to determine the need for a replacement dose of UDENYCA if they suspect that the device may not have performed as intended.
- Aortitis: Has been reported in patients receiving pegfilgrastim products, occurring as early as the first week after start of therapy. Manifestations may include generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count). Consider aortitis when signs and symptoms develop without known etiology. Discontinue UDENYCA® if aortitis is suspected.
- Nuclear Imaging: Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. Consider when interpreting bone imaging results.

ADVERSE REACTIONS: Most common adverse reactions (≥ 5% difference in incidence compared to placebo) are bone pain and pain in extremity.

To report SUSPECTED ADVERSE REACTIONS, contact Coherus BioSciences at 1-800-4-UDENYCA (1-800-483-3692) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full Prescribing Information available at www.UDENYCA.com

1. Neulasta prescribing information
2. UDENYCA prescribing information

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.

Coherus' immuno-oncology pipeline 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 is a novel anti-IL-27 antibody currently being evaluated in two on-going 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, ADCC-enhanced anti-CCR8 antibody currently in a Phase 1/2 study as a monotherapy in patients with advanced solid tumors.

Coherus' earlier-stage immuno-oncology pipeline targets immune-suppressive mechanisms, including CHS-006, a TIGIT-targeted antibody, being evaluated in a Phase 1/2 clinical trial in combination with LOQTORZI 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®, YUSIMRY™ (adalimumab-aqvh), a biosimilar of Humira® and plans to launch LOQTORZI™ (toripalimab-tpzi), a novel next generation PD-1 inhibitor, in the U.S. in January 2024.

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 launch UDENYCA® ONBODY, maintain Coherus' commercial capabilities and identify synergies between its commercial capabilities and its immuno-oncology pipeline; Coherus' expectations that its immuno-oncology product candidates will enhance patient outcomes; Coherus' projections about the demand for UDENYCA® ONBODY and its reception after it is launched.

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 September 30, 2023, filed with the Securities and Exchange Commission on November 6, 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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