Coherus Announces Positive Results of UDENYCA® On-Body Injector Clinical Trial

- UDENYCA® On-Body Injector (OBI) Achieved Both Pharmacokinetic and Pharmacodynamic Bioequivalence in Randomized Clinical Trial

- Coherus plans to seek U.S. marketing authorization for the UDENYCA® OBI in 2022

REDWOOD CITY, Calif., Oct. 05, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("the Company"; Nasdaq: CHRS) today announced positive results from a randomized, open-label, crossover study assessing the pharmacokinetic (PK) and pharmacodynamic (PD) bioequivalence of UDENYCA® (pegfilgrastim-cbqv) administered via a proprietary on-body injector (OBI) device compared to the currently marketed UDENYCA® pre-filled syringe (PFS). The study met all PK bioequivalence primary endpoints as well as the key secondary pharmacodynamic endpoint of ANC (absolute neutrophil count). No new safety signals were observed. The study enrolled 189 subjects randomized 1:1 to receive one of two treatment sequences of UDENYCA®: OBI followed by PFS, or the reverse, with a treatment interval of 6 to 8 weeks.

Coherus plans a 2022 submission to the United States Food and Drug Administration (FDA) of a prior approval supplement to seek marketing authorization for the UDENYCA® OBI and anticipates a standard 10-month review period. Coherus expects commercial launch of the UDENYCA® OBI directly post approval.

"UDENYCA® quickly became the top-selling pre-filled syringe pegfilgrastim in the U.S. within months of launch in 2019, establishing Coherus as a trusted partner to oncologists and demonstrating the power of biosimilar competition to expand patient access to an important cancer medicine," said Denny Lanfear, CEO of Coherus. "With our OBI program progress, we are excited by the potential to offer to providers and patients a new on-body injector presentation of UDENYCA®, if approved, and to compete directly with Neulasta® Onpro®, which retains more than 50% share of the overall pegfilgrastim market."

An FDA-approved UDENYCA® OBI would offer providers a highly desired alternative to the originator's on-body pegfilgrastim delivery system and eliminate the need for patients to return to a hospital or other clinical setting the day after chemotherapy to receive UDENYCA®.

About UDENYCA®

UDENYCA® is the #1 prescribed pegfilgrastim pre-filled syringe in the United States.

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.

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

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.

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 10^9/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.

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

About Coherus BioSciences
Coherus is a commercial stage biopharmaceutical company with the mission to increase access to cost-effective medicines that can have a major impact on patients' lives and to deliver significant savings to the health care system. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. For additional information, please visit www.coherus.com.

Coherus markets UDENYCA® (pegfilgrastim-cbqv) in the United States and through 2023 expects to launch toripalimab, an anti-PD-1 antibody, as well as biosimilars of Lucentis®, Humira®, and Avastin®, if approved.

UDENYCA® is a trademark of Coherus BioSciences, Inc.

Avastin® and Lucentis® are registered trademarks of Genentech, Inc.

Humira® is a registered trademark of AbbVie 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, Coherus' plans to submit a prior approval supplement for the UDENYCA on-body injector in 2022; Coherus' expected timeline for the FDA's review period; Coherus' ability to gain approval for the UDENYCA on-body injector presentation; Coherus' plans to launch the UDENYCA on-body injector upon approval; Coherus' ability to compete successfully against another pegfilgrastim on-body injector device; Coherus' ability to generate cash flow from its UDENYCA ® business; the potential for Coherus to gain approval for other biosimilar products or for toripalimab in the United States; Coherus' plans to invest the cash generated by its biosimilar commercial business to build a focused immuno-oncology franchise; Coherus' ability to prepare for projected launches through 2023 of toripalimab and of biosimilars of Humira®, Avastin® and Lucentis®, if approved.

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; the risks and uncertainties of the regulatory approval process, including the timing of Coherus' regulatory filings; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' drug candidates; and the risks and uncertainties of possible patent litigation. All forward-looking statements contained in this press release speak only as of the date on which they were made. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the 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 year ended December 31, 2020, filed with the Securities and Exchange Commission on February 25, 2021, its Quarterly Report on Form 10-Q for the three and six months ended June 30, 2021, filed with the Securities and Exchange Commission on August 5, 2021 and its future periodic reports to be filed with the Securities and Exchange Commission. Results for the quarter ended June 30, 2021, are not necessarily indicative of our operating results for any future periods.

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