Coherus Announces U.S. Launch of UDENYCA® Autoinjector

May 22, 2023

– UDENYCA® AI is the only pegfilgrastim prefilled autoinjector product presentation available in the U.S. that can be administered either in-office or at-home –

– UDENYCA® AI fulfills high unmet need by giving providers a new, innovative option that offers patients greater choice, independence and flexibility –

REDWOOD CITY, Calif., May 22, 2023 (GLOBE NEWSWIRE) -- **Coherus BioSciences, Inc.** ("Coherus", Nasdaq: CHRS), today announced that the single-dose (6mg/0.6mL), prefilled autoinjector presentation of UDENYCA® (pegfilgrastim-cbqv) is now available for commercial sale in the United States. UDENYCA® is a pegfilgrastim biosimilar administered the day after chemotherapy to decrease the incidence of infection as manifested by febrile neutropenia.[1] UDENYCA® AI's streamlined design offers a simple option for in-office and at-home settings of care that administers pegfilgrastim in less than 10 seconds.[2]

"Those independent patients, with families and busy lifestyles, or those who just have a hard time coming back to the office the day after chemotherapy—that's who is really going to benefit from the introduction of the UDENYCA® autoinjector," said Francis Arena, M.D., Medical Director, NYU Langone Arena Oncology. "This gives us more choice in meeting our patients' needs, and the simple administration gives confidence in at-home administration."

"Patients have indicated in market research that quick administration, ease of use, and a sense of control and independence were the features and benefits of the autoinjector most important in their decision-making when choosing an at-home administration option. With UDENYCA AI, providers now have a new option that offers their patients where and how to receive their therapy, and health plans have a new option to increase access for patients," said Paul Reider, Chief Commercial Officer of Coherus. "Our goal is to be the only pegfilgrastim product offering value across three differentiated presentations, fully meeting market needs and creating a durable franchise positioned to maximize market share growth. UDENYCA® AI represents substantial progress in that direction, and UDENYCA® will become the only pegfilgrastim product with three presentation options with the launch of our proprietary on-body injector later this year, if approved."

"Innovating to address patient needs is core to our mission, and we believe UDENYCA® AI has the potential to ease the journey for patients battling cancer," said Denny Lanfear, Chief Executive Officer of Coherus.

UDENYCA® AI has user-friendly features that promote successful delivery. The approval of UDENYCA® AI was supported by a comprehensive analytical data package, as well as a clinical study demonstrating the pharmacokinetic, pharmacodynamic bioequivalence and a comparable safety profile (including immunogenicity) of UDENYCA administered with the AI versus the prefilled syringe.[3]

UDENYCA® AI is available through existing full-line and specialty distributors and will be priced at parity to the UDENYCA® prefilled syringe at a list price of $4,175.00 which represents a 35% discount[4] from the list price of the reference product. Billing under the medical benefit for UDENYCA® AI is streamlined as it has the same permanent, product-specific Q-Code as the prefilled syringe, Q5111, and a unique NDC number of 70114-0120-01. UDENYCA Solutions™ offers healthcare professionals comprehensive practice and patient support that includes extensive patient assistance and office support to ensure successful access and reimbursement.

About UDENYCA®

UDENYCA® is the only pegfilgrastim product offering two on-demand options—prefilled syringe and autoinjector, with a third, proprietary on-body injector (OBI) under review by the FDA. If approved, the UDENYCA® OBI would offer providers a highly desired alternative to the originator's on-body pegfilgrastim delivery system. Unlike other pegfilgrastim products, UDENYCA® is manufactured in the United States and therefore is well-positioned to meet market demand. Since 2019, over 263,000 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.
- 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.
- 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 focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics.

In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. The Biologics License Application for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma is currently under review by the FDA.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, and CIMERLI®(ranibizumab-eqrn), a biosimilar of Lucentis®, in the U.S., and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the U.S. in 2023.

References: 1. UDENYCA® (pegfilgrastim-cbqv) Prescribing Information. Redwood City, CA: Coherus BioSciences, Inc.; 2023.; 2. Ypsomed Delivery Systems. YpsoMate website. March 31, 2022. https://yds.ypsomed.com/en/injection-systems/auto-injectors/ypsomate.html. Accessed January 12, 2023.; 3. Data on file. Coherus BioSciences, Inc. 2023.; 4. Savings per dose based on the wholesale acquisition cost of UDENYCA® vs Neulasta® as of April 2023.

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 build its immuno-oncology franchise to achieve a leading market position; Coherus' ability to generate cash; Coherus' investment plans; Coherus' expectations for the launch date of YUSIMRY™ and other products and expectations for any future product approvals; Coherus' projections about the benefits that UDENYCA® AI may provide; and Coherus' expectations for the success of UDENYCA® AI.

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 the COVID-19 pandemic; 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; the risk of Coherus' execution of its change in strategy from a focus on biosimilars to a strategy using cash from its portfolio to fund an oncology franchise; 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 March 31, 2023, filed with the Securities and Exchange Commission on May 8, 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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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/106d556f-f9b4-4c2d-8937-0d717ea5758e

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