FDA Approves UDENYCA® Autoinjector

Mar 6, 2023

- UDENYCA® is the only pegfilgrastim therapy delivered in a convenient, easy-to-administer prefilled autoinjector to offer in-clinic and at-home administration options for cancer patients undergoing myelosuppressive chemotherapy -

- An additional presentation, the UDENYCA® proprietary on-body injector (OBI) device, is under review by the FDA with anticipated approval this year -

REDWOOD CITY, Calif., March 06, 2023 (GLOBE NEWSWIRE) -- **Coherus BioSciences, Inc.** ("Coherus", Nasdaq: CHRS), today announced that the U.S. Food and Drug Administration ("FDA") approved a single-dose, prefilled autoinjector presentation of UDENYCA ® (pegfilgrastim-cbqv), a biosimilar pegfilgrastim administered the day after chemotherapy to decrease the incidence of infection as manifested by febrile neutropenia. The UDENYCA® autoinjector has a streamlined, easy-to-use design for use in both in-office and at-home settings of care.

"The introduction of the autoinjector option for UDENYCA ®, with the ability to be administered at home or in the doctor's office, will provide increased choice and control for patients and physicians, ultimately making treatment more accessible to patients," said Dr. Lee Schwartzberg, Chief of Medical Oncology and Hematology at the Renown Health William N. Pennington Cancer Institute, and Professor of Clinical Medicine, University of Nevada. "There are certain types of cancer patients, those who live far away, have an active lifestyle, or who are supporting the needs of a busy family, for whom this option eliminates the need to return to the clinic and enables them to choose the time and place for treatment without having to wear an on-body device."

"The UDENYCA ® autoinjector represents the first innovation in the pegfilgrastim space in eight years and highlights Coherus' commitment to developing innovative solutions that expand access and address the needs of patients undergoing cancer treatment," said Denny Lanfear, CEO of Coherus.

The UDENYCA® autoinjector (AI) is an intuitive design with administration triggered by push-on-skin activation, immediately and reliably delivering a complete pegfilgrastim dose. The approval of UDENYCA® AI was supported by a comprehensive analytical data package, as well as a pharmacokinetic, pharmacodynamic and immunogenicity study.[1]

Commercial availability of UDENYCA® AI is planned for the second quarter of 2023.

About UDENYCA®

UDENYCA® is the only pegfilgrastim brand offering two on-demand options—prefilled syringe (PFS) and AI providing more choice and flexibility customized to meet the needs of patients and practices. UDENYCA® (pegfilgrastim-cbqv) administered via a proprietary on-body injector (OBI) device is under review by the FDA. If approved, UDENYCA® OBI would offer providers a highly desired alternative to the originator's on-body pegfilgrastim delivery system. Since its launch in 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.

1. Coherus data on file.

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™, UDENYCA® AI and other products; Coherus' projections about how desirable UDENYCA ® OBI may be to providers; 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' Annual Report on Form 10-K for the year ended December 31, 2022, to be filed with the Securities and Exchange Commission on or about March 6, 2023, including the section therein captioned "Risk Factors" and in other documents that Coherus files with the Securities and Exchange Commission.

affiliates, related companies or its licensors or joint venture partners unless otherwise noted. Trademarks and trade names of other companies appearing in this press release are, to the knowledge of Coherus, the property of their respective owners.

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

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/c7c3042f-4ff2-4417-8018-c2c65d627f93

Source: Coherus BioSciences, Inc.