U.S. FDA Approves UDENYCA™ (pegfilgrastim-cbqv)

REDWOOD CITY, Calif., November 2, 2018 – Coherus BioSciences, Inc. (NASDAQ: CHRS), today announced that the U.S. Food and Drug Administration (FDA) has approved UDENYCA™ (pegfilgrastim-cbqv), the first pegfilgrastim biosimilar approved by both the FDA and the European Commission (EC) for patients with cancer receiving myelosuppressive chemotherapy. UDENYCA™ is Coherus' first drug to receive FDA or EC approval.

"We are excited to announce that Coherus has received FDA approval for UDENYCA. I want to thank the Coherus team, our strategic partners, and the U.S. Food and Drug Administration for this extraordinary achievement," said Denny Lanfear, Chairman, CEO and President of Coherus BioSciences. "The list price of Neulasta has nearly tripled since approval in 2002 and now represents a $4 billion annual cost burden in the U.S. We believe that competition is essential in controlling burdensome price increases, and UDENYCA will play an important role in curbing that spend when launched. Our in-depth understanding of the market will allow us to deliver significant value to patients, payors, and providers in the U.S., including 340B hospitals, small clinics and small hospitals."

"For a number of reasons we believe the oncology marketplace is ideal for biosimilars, and we are committed to a vigorous product launch," said Chris Thompson, Senior Vice President of Sales. "Our oncology-focused, highly capable and fully-staffed commercial team is in place. We are confident that our U.S.-based manufacturing network has the finished goods in inventory to meet our highest expected demand for an extended period."

The approval of UDENYCA™ was supported by a comprehensive analytical similarity package, as well as pharmacokinetic, pharmacodynamic and immunogenicity studies, including over 600 healthy subjects.

"UDENYCA's robust clinical package includes a dedicated immunogenicity similarity study in over 300 healthy subjects," said Barbara Finck, M.D., Chief Medical Officer of Coherus BioSciences. "In support of that study, and as part of our commitment to ensuring patient safety, we deployed a battery of sensitive immunogenicity assays. This effort not only supported the biosimilarity of UDENYCA, but also advanced the understanding of the immunogenic response of pegfilgrastim products."

The European Commission approved UDENYCA™ on September 21, 2018.

The company will provide additional details with respect to pricing and launch timing on the November 8 earnings call.

About UDENYCA™

UDENYCA™ (pegfilgrastim-cbqv), formerly CHS-1701, is a PEGylated growth colony-stimulating 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. UDENYCA™ drug substance manufacturing is located in Boulder, Colorado. Pegfilgrastim is one of the largest selling oncology biologics with worldwide revenues in excess of $4.5 billion in 2017.

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.

Limitations of Use

UDENYCA™ is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION: Patients with a history of serious allergic reaction to human granulocyte colony-stimulating factors such as pegfilgrastim or filgrastim products.

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:*** Permanently discontinue UDENYCA™ in patients with serious allergic reactions.
- ***Fatal sickle cell crises:*** Have occurred.
- ***Glomerulonephritis:*** Evaluate and consider dose-reduction or interruption of UDENYCA™ if causality is likely.

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, Inc.
Coherus is a leading biosimilar company that develops and commercializes high-quality therapeutics for major regulated markets. Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is commercializing UDENYCA™ (pegfilgrastim-cbqv), advancing two late-stage clinical products towards commercialization, CHS-1420 (adalimumab biosimilar) and CHS-0214 (etanercept biosimilar), as well as developing a robust pipeline of future products in ophthalmology (including CHS-3351, a ranibizumab biosimilar, and CHS-2020, an aflibercept biosimilar), and CHS-131, a small molecule for nonalcoholic steatohepatitis (NASH) and multiple sclerosis. For additional information, please visit www.coherus.com.

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' ability to manufacture and promote UDENYCA™ in the United States, to execute on a commercial launch of UDENYCA™, to curb spending on Neulasta by commercializing UDENYCA™, and to supply sufficient volume of UDENYCA™ to meet product demand. 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' biosimilar 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' Quarterly Report on Form 10-Q for the three and six months ended June 30, 2018.

CONTACT:
David S. Arrington
VP, Communications, Investor Relations and Government Relations
Coherus BioSciences, Inc.
darrington@coherus.com
+1 (650) 395-0196