Coherus BioSciences Receives European Commission Approval for UDENYCA™ (Pegfilgrastim Biosimilar)

REDWOOD CITY, Calif., Sept. 25, 2018 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq: CHRS), today announced the European Commission (EC) has granted marketing authorization to UDENYCA™ (formerly CHS-1701), a pegfilgrastim (Neulasta®) biosimilar. UDENYCA™ is one of the first pegfilgrastim biosimilars to gain marketing authorization in Europe.

"Today's EC approval decision is the first marketing authorization for Coherus, an important step forward in realizing our mission of increasing access to biologic treatments to patients globally," said Denny Lanfear, President and CEO of Coherus BioSciences. *"This decision is the result of a concerted effort across analytical, process, manufacturing and clinical/regulatory, as well as intellectual property, the pillars of our product platform. I would like to congratulate my team and our partners for their dedication and extraordinary efforts in achieving this significant milestone."*

"We look forward to the anticipated US approval later this year and to executing on a vigorous launch, supported by our strategic manufacturing partners in the United States, meeting the highest product quality and production reliability standards," said Vince Anicetti, Chief Operating Officer of Coherus BioSciences.

UDENYCA™ is currently under evaluation by the U.S. Federal Drug Administration (FDA) with an action date of November 3, 2018.

About UDENYCA™
UDENYCA™ (pegfilgrastim-cbqv), formerly CHS-1701, is a growth-colony-stimulating-factor designed to decrease the chance of infection as manifested by febrile neutropenia (fever, often with other signs of infection, associated with an abnormally low number of infection-fighting white blood cells), in patients with non-myeloid (non-bone marrow) cancer who are receiving myelosuppressive chemotherapy that has 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.

UDENYCA ™ is not yet available for commercial sale.

For more information about UDENYCA ™ contact Coherus BioSciences Medical Information at (800) 4-UDENYCA (1-800-483-3692)

Neulasta® is a registered trademark of Amgen Inc.

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. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production, sales & marketing and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is advancing three late-stage clinical products towards commercialization, UDENYCA™ (pegfilgrastim biosimilar), 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 receive approval for UDENYCA™ from the U.S. Food and Drug Administration in the United States, to execute on a commercial launch of UDENYCA™, to meet product quality and production reliability standards, and to increase access to biologic treatments to patients globally. 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, filed with the Securities and Exchange Commission on August 8, 2018 and its future periodic reports to be filed with the Securities and Exchange Commission.

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