Coherus BioSciences Receives Positive CHMP Opinion for UDENYCA™ (Pegfilgrastim Biosimilar Candidate)

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REDWOOD CITY, Calif., July 27, 2018 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for the marketing authorization of UDENYCA™ (formerly CHS-1701), a pegfilgrastim (Neulasta®[1]) biosimilar candidate. UDENYCA has the opportunity to become one of the first pegfilgrastim biosimilars to gain Marketing Authorization in Europe.

"The positive opinion issued by the CHMP today is a significant milestone for Coherus, as it validates both our UDENYCA biosimilarity package as well as our development platform as a whole," said Denny Lanfear, President and CEO of Coherus BioSciences. *"We believe UDENYCA will represent an important option for patients, providers and payers seeking alternatives for the treatment and prevention of febrile neutropenia due to cytotoxic chemotherapy in Europe."*

UDENYCA's marketing authorization application to EMA is supported by analytical similarity data, a 3-arm, triple-crossover pharmacokinetic (PK) and pharmacodynamics (PD) study in healthy subjects, as well as a robust immunogenicity package including a dedicated immunogenicity study in over 300 subjects.

"UDENYCA is clinically differentiated with positive PK/PD and immunogenicity studies in over 600 healthy subjects," said Barbara Finck, M.D., Chief Medical Officer of Coherus BioSciences. *"We have worked in a harmonized fashion with the EU and U.S. regulatory authorities, and continue to work with the FDA toward our expected November action date."*

The European Commission decision on the approval for UDENYCA is expected in October. UDENYCA is currently under evaluation by the U.S. Federal Drug Administration (FDA) with an action date expected on or before November 3, 2018.

[1] Neulasta® is a registered trademark of Amgen Inc.

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

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), as well as 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 European Commission and to receive approval from the U.S. Food and Drug Administration in the United States. 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 period ended March 31, 2018, filed with the Securities and Exchange Commission on May 10, 2018 and its future periodic reports to be filed with the Securities and Exchange Commission.

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